IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

RAMONA WINEBARGER and REX WINEBARGER,
Plaintiffs,

CASE NOS. 5:15CV57-RLV; 3:15CV211-RLV

v.
BOSTON SCIENTIFIC CORPORATION,
Defendant

MARTHA CARLSON,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION
Defendants

PLAINTIFFS OBJECTIONS AND COUNTER DESIGNATIONS TO DEFENDANT BOSTON SCIENTIFIC'S DEPOSITION DESIGNATIONS OF MICHAEL J. KENNELLY, M.D. TAKEN JULY 2, 2014

BSC Designations	Objection	Plaintiffs Counter Designation
mk070214, (Pages 7:3 to 10:3) 7 3 THE VIDEOGRAPHER: Starting of Number 1 4 on the record at 5:39 p.m. This is the videotaped 5 deposition of Dr. Michael Kennelly. This is in the 6 United States District Court for the Southern 7 District of West Virginia, Charleston Division, MDL 8 Number 2326, Case Number 2:13-CV-5475. Today's 9 date and time are indicated on the video screen. 10 We are located today at 2001 Vail 11 Avenue in Charlotte, North Carolina. The court 12 reporter today is Cindy Hayden. My name is Scott 13 Swing. I'm the videographer. We're both here on 14 the behalf of Golkow Technologies out of 15 Philadelphia, Pennsylvania. 16 At this time, counsels will verbally 17 introduce themselves and who they represent, 18 starting with the noticing attorney first, please. 19 MR. SULLIVAN: My name is Kevin 20 Sullivan, and I represent the Defendant, Boston 21 Scientific Corporation. 22 MR. FABRY: John Fabry. I represent 23 the Plaintiff, Martha Carlson.		

THE VIDEOGRAPHER: At this time, the court reporter will swear the witness for the

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record, please.
* * *
MICHAEL J. KENNELLY, M.D.
being first duly sworn, testified as follows:
* * *
THE VIDEOGRAPHER: We may proceed.
EXAMINATION
BY MR. SULLIVAN:
Q. Sir, would you please state your full name.
A. Michael Joseph Kennelly.
Q. Doctor, what's your profession?
A. Urology with subspecialization in female pelvic medicine, reconstructive surgery.
Q. And what is your professional address?
A. 2001 Vail Avenue, Suite 360, Charlotte, North Carolina, but I also have two other addresses.
Q. Okay. What are those?
A. One is at McKay Urology. I think it's 1025 Edgehill Road South, Charlotte, North Carolina, and then the third is at 1100 Blythe Boulevard, Carolinas Rehabilitation, Charlotte, North Carolina.
Q. Okay. Doctor, I'm going to be asking

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you a series of questions today relating to Martha Carlson and the care and treatment you provided to her back in the 2010 time frame. If at any time you don't understand one of my questions today or you need the question repeated for any reason, please just verbally tell me to do that and I will, okay?
A. Okay.
Q. Secondly, if at any time you're tired and you want to take a break for any reason, if you need to respond to a page or call or anything like that, again, just tell us and we'll let you do that, okay?
A. Okay.
Q. Is there any reason, sir, you won't be able to give accurate, complete, truthful testimony today?
A. No.
Q. You understand you're here today to testify about your care and treatment of Martha Carlson and her surgery on July 16th, 2010?
A. Yes.
Q. You understand you're not a defendant in this case?
A. Yes.

10 1 Q. And you understand that Boston 2 Scientific has not made any claims against you? 3 A. Yes.		
mk070214, (Pages 12:14 to 12:20) 12 14 Q. And, sir, have you and I ever met 15 before today? 16 A. No. 17 Q. Okay. Have you ever met with any 18 attorney representing Boston Scientific Corporation 19 regarding this case? 20 A. No.		
mk070214, (Pages 14:14 to16:8) 14 14 Q. We've marked as Exhibit Number 2 a 15 stack of documents, and the heading on the top of 16 the first page of that exhibit says McKay Urology 17 at the top. What are those documents? 18 A. Those are the office notes from McKay 19 Urology specific to the patient, Martha Carlson. 20 Q. Okay. Is McKay Urology your private 21 practice? 22 A. I have three practices. 23 Q. Okay. 24 A. That's one of the practices. 25 Q. All right. So you practice urology at 15 1 McKay Urology, yes? 2 A. Yes. 3 Q. All right. And is that where you saw 4 Ms. Carlson? 5 A. Correct. 6 (Kennelly Exhibit 3, Informed Consent 7 Forms, was marked for identification.) 8 BY MR. SULLIVAN: 9 Q. All right. Exhibit Number 3, sir, what 10 is that? 11 A. This is consent forms for Ms. Carlson 12 that were from McKay Urology. 13 Q. Okay. Are those the informed consent 14 forms for her -- for the surgery that you performed 15 on July 16th, 2010? 16 A. Correct. 17 (Kennelly Exhibit 4, Billing records 18 for Mrs. Carlson, was marked for identification.) 19 BY MR. SULLIVAN: 20 Q. Okay. And then we've marked other 21 documents previously as Exhibit Number 4. Can you 22 tell me what those are? 23 A. These are the billing records for 24 Mrs. Carlson. 25 (Kennelly Exhibit 5, Curriculum Vitae 16 1 of Michael Joseph Kennelly, M.D., was marked for		

identification.)
BY MR. SULLIVAN:
Q. And Exhibit Number 5 is a copy of your curriculum vitae?
A. Correct.
Q. Is that up to date, sir?
A. In 2014.

mk070214, (Pages 17:3 to 21:12)

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Q. All right. Did you produce any documents in connection with the cross-notice of the videotaped deposition?
A. Yes.
Q. Okay. Do you have those with you?
A. Correct.
Q. Okay. Could I see those?
A. So things that they had requested. So copy of the bibliography, that's in the CV; copy of any list identifying previous testimony by deposition or trial, if available. I don't have that available.
Any documents ever provided to you by defendant in regard to any of their products, including, but not limited, Boston Scientific Uphold vaginal support system, directions for use, IFU, patient brochures, marketing literature, sales literature, implantation videos, any and all correspondence with you and defendant.
In regards to that, you know, I do have documentation from Boston Scientific that is sort of faculty guide that includes a lot of that information that's in here.

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Q. Okay. So why don't we mark the Cross-Notice of Deposition as the next exhibit.
We'll mark that as Exhibit Number 8.
(Kennelly Exhibit 8, Cross-Notice of Videotaped Deposition of Dr. Michael Kennelly, was marked for identification.)
BY MR. SULLIVAN:
Q. And have you brought with you today all documents in your possession that responds to Schedule A of Exhibit 8?
A. As far as some that are in my possession, correct. They also wanted -- you know, just completing what they wanted, any documents or agreements between you and defendant, Boston Scientific, including consulting, training or other services. So I do have the contracts from Boston Scientific.
Q. Okay.
A. And then they wanted any and all documents showing payments made to you by defendant, Boston Scientific. The only ones I

could come up with are basically 2011. Our hard drive crashed at home, so prior to that, I don't have those; but this is payments from 2011 up until now.

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Q. All right.
A. So those are the most current from 2011. And any copies of all expert reports you prepared. I've not prepared any.
Q. All right. So let's mark these documents on the record. The contracts are these three documents here, correct?
A. Those are -- correct. So the first two are actually executed documents. The last document is not executed.
Q. Okay.
A. But I have received it from Boston Scientific.
(Kennelly Exhibit 9, Contract with Boston Scientific dated 6/1/09, was marked for identification.)
(Kennelly Exhibit 10, Contract with Boston Scientific dated 8/3/11, was marked for identification.)
(Kennelly Exhibit 11, Unexecuted Contract with Boston Scientific dated 6/26/14, was marked for identification.)
BY MR. SULLIVAN:
Q. All right. So we'll mark those -- mark the June 1st, 2009, cover letter document that you

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referred to as a contract as Exhibit Number 9; the August 3rd, 2011, cover letter documents as Exhibit Number 10; the June 26th, 2014, cover letter, this is the one you said was not executed?
A. Correct.
Q. We'll mark that as Exhibit Number 11. And the documents regarding payments, which are two confirmation of service packets and one 1099 form, correct?
A. Correct.
(Kennelly Exhibit 12, Confirmation of Service dated 9/25/11, was marked for identification.)
(Kennelly Exhibit 13, Confirmation of Service dated 10/16/11, was marked for identification.)
(Kennelly Exhibit 14, 2011 1099, was marked for identification.)
(Kennelly Exhibit 15, Pelvic Floor Institute, Women's Health Business of Boston Scientific Faculty Guide dated June 2010, was marked for identification.)
BY MR. SULLIVAN:
Q. All right. So we'll mark the confirmation of service documents as Exhibit

21 1 Number 12 will be the one with the date 9/25/11 on 2 it. 3 Exhibit Number 13 will be the 4 confirmation of service documents with the date 5 10/16/11. 6 And the 1099 form we'll mark as Exhibit 7 Number 14. 8 All right. And this binder that's 9 labeled Pelvic Floor Institute, Women's Health 10 Business of Boston Scientific, Faculty Guide, June 11 2010, this appears to be your original, correct? 12 A. Correct.		
mk070214, (Pages 22:8 to 39:4) 22 8 Q. All right. Sir, with respect to the 9 office notes, consent forms that were marked as 10 Exhibits Number 2 and 3 tonight, were these records 11 made at or near the time of your treatment of 12 Ms. Carlson? 13 A. Correct. 14 Q. And were they created by persons with 15 knowledge of the events described in the records? 16 A. Correct. 17 Q. And was it your regular practice to 18 create such records in connection with your 19 practice? 20 A. Yes. 21 Q. And are those records kept and created 22 as regularly -- regular activity associated with 23 your business of practicing medicine? 24 A. Yes. 25 Q. Other than the documents that you've 23 1 produced for us and that we've marked as exhibits, 2 do you know of any other documents that pertain to 3 your care and treatment of Ms. Carlson? 4 A. No, I do not. 5 Q. Doctor, before we get directly into 6 your care and treatment of Ms. Carlson, can you 7 tell us generally what pelvic organ prolapse is? 8 A. So, pelvic organ prolapse is a 9 condition whereby the pelvic organs within the 10 female, typically the uterus, the bladder, the 11 rectal area, the peroneum and urethra have lost 12 support. And it includes a combination of 13 different support possible defects. 14 In the urethral area could be involved 15 in a urethrocele hypermobility leading to stress 16 urinary incontinence. In the anterior vaginal wall 17 it oftentimes leads to relaxation of a cystocele, 18 which could be a central or paravaginal defect. In 19 the uterus area, the uterine area tends to drop. 20 In the posterior compartment, it's a weakening of 21 the rectovaginal fascia for a rectocele to develop.		

Q. Okay. So if we use the terms cystocele tonight, that refers to a bladder prolapse, correct?
A. That's anterior vaginal wall prolapse.

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Q. Okay. Where the bladder bulges into the vagina?
A. Correct. But there's also the urethra, so it could include a urethrocele also.
Q. Okay. And a rectocele again is what?
A. Is a posterior vaginal wall relaxation, so weakening of the posterior wall of the vagina.
Q. Okay. And does that result in a, again, bulge into the vaginal area?
A. Correct.
Q. Okay. And which organ bulges into the vaginal area with rectocele?
A. It can be a -- could be the rectum. It could be a piece of small bowel, such as an enterocele.
Q. Okay. And can you tell us, Doctor, what are the symptoms that are typically associated with pelvic organ prolapse?
A. It can be a variety of symptoms based on, you know, the individual patient. Several patients do complain of heaviness, feeling a sensation of fullness. If they do a lot of standing, lifting, straining, they can complain of back pain, discomfort. Majority of times, patients notice where they see a visible bulge coming from

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the vaginal area when they're wiping.
Q. Okay. Can pelvic organ prolapse be asymptomatic?
A. Absolutely.
Q. Okay. And in the more severe cases, Doctor, what symptoms would you expect to see?
A. Well, severity is not based on prolapse, meaning the degree of prolapse. So that's what -- severity as far as how far the bulging is doesn't have any correlation to severity. So it's really individualized for the patient.
Q. All right. And so are there different symptoms you would use to gauge severity?
A. Well, the -- the difficulty is, within the pelvic area, there are several different organs within that area. So if you have an organ that's around that area that may be involved due to traction, pulling, you may think that it's due to prolapse, but it may actually be due to the intrinsic dysfunction for that organ.
For example, patients may complain of urgency, frequency, needing to go to the rest room,

and they may have also prolapse on exam. But, in reality, it may be the prolapse contributing, but

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it may also be not the prolapse. There are several patients that have that similar condition without prolapse.
So the exact symptoms that people are describing, it makes it challenging. If someone is talking on defecatory symptoms of constipation, straining, difficulty with bowel movements, that could be a neurological component that has to do with the neuromuscular aspect of the rectal area as opposed to true bulging effect.
So differential diagnosis evaluation trying to associate their symptoms from a vaginal bulge is sometimes difficult.
Q. Do you use any type of grading system to stage or describe the severity of pelvic organ prolapse in patients?
A. Well, there are two types of systems that have been utilized. One is the Baden-Walker System and one is also the POP-Q System. So those are the two different types.
Q. Okay. Do you use both those types?
A. I do, depending on kind of what we're utilizing it for. If we're doing research studies, oftentimes, they would like us to use the POP-Q System. I personally find that the Baden-Walker

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System is a more individualized patient friendlier system that's easier to comprehend when you're talking amongst other clinicians.
Q. Can you tell us generally how the Baden-Walker System is applied?
A. Right. So, typically, the Baden-Walker System is you identify which compartment you're talking about, whether anterior, apical or posterior. And if it is less than halfway down the vaginal area, that would be Grade I. Grade II is when it's to the vaginal opening. Grade III is when it's beyond the opening, and Grade IV is when you've had total -- total evolved prolapse.
Q. Okay. So in the Baden-Walker System, the Grade I would be less severe than the Grade III or Grade IV?
A. Correct.
Q. All right. How do you perform the POP-Q?
A. So, the POP-Q is a challenging type of exam that looks at different areas. So, the first part is identifying a point that is minus 3 centimeters from the vaginal opening. And that's on, let's say, the anterior wall. That is a fixation point. And as the patient is in lithotomy

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position straining, you try to identify from the vaginal opening where that minus 3 point lands. If it stays stable at minus 3, then that point is called AAs minus 3.
If you then look at -- the next point would be BA, which is actually the most distal extent on straining. It doesn't say the exact location of that area. The next point you're looking at is where the cervical cuff is, measuring from the vaginal opening.
Then they do the same on the posterior compartment. You couple that with a couple other measures, a genital hiatus measurement, a peritoneal body measurement, and then based on that system, if it is from the farthest or if it's to minus 2 centimeters from the vaginal opening, that is Grade I, doesn't distinguish what compartment it is whatsoever, anterior, apical or posterior; if it is between plus 1 and -- or minus 1 and plus 1, that is Stage II; if it is between plus 1 and just out to the extent of the total aversion, that would be Stage III, and then Stage IV is eversion.
But the challenge with that system is that it's a very measurement-oriented system with a lot of numbers and it's great for research, it's

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great for capturing population based aspects; but on the individual patient, it may not have as much sort of clinical application.
Q. Okay. So is the general idea of the POP-Q to sort of measure how far the organ -- the prolapsed organ has dropped from its normal position?
A. Correct. However, there's a lot of variability within that because your technique of measuring one inter -- interobserver variation adapts when the patient is actually straining and how well they strain is different also.
Q. So different positions might get a different measurement, different day?
A. Correct.
Q. And you mentioned -- just to clarify, you mentioned the lorthotic [sic] position. Can you describe what that is?
A. So lithotomy position, basically where you're lying on your back where your legs are elevated typically in stirrups.
Q. Okay. And you referred to apical, anterior and posterior compartments?
A. Correct.
Q. Can you describe what those are?

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A. Right. So the anterior compartment

would include the vaginal wall that is covering over the urethra and the bladder. The apical compartment typically covers the cervix and uterus. In a post hysterectomized patient, it would just include the top part of the vaginal area. And then the posterior vaginal wall encovers the rectum and possibly some of the small intestines.
Q. And in your practice, have you treated many patients with pelvic organ prolapse?
A. Yes.
Q. Is that a common complaint in your patient population?
A. Correct.
Q. And how does pelvic organ prolapse affect or impact the quality of a woman's life?
A. It can impact it in a variety of different ways. It can be from the spectrum where it doesn't impact them at all versus to the point where it becomes debilitating. So depending on either the amount of prolapse or the amount of symptoms that go along with it, it's up to that individual patient to kind of decide for herself, you know, where it fits in.

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Q. Does pelvic organ prolapse typically improve without treatment?
A. For people with mild prolapse, it can oftentimes improve if they're just trying to improve their general physical health. If they're trying to improve their core, which a lot of ladies will do, sometimes that's with exercise training, they can improve the tone. If -- if they've recently delivered a child, just due to the stretch, the elasticity of the -- the muscles and the surrounding structures, in time, it oftentimes will improve. In general, for the older patient who is not trying to change their health in any way, it likely does not improve; but it may not worsen.
Q. Okay. Does it typically, though, get worse over time for those patients?
A. It's -- it's variable. We don't have a crystal ball.
Q. Are there certain -- I think you touched on some of them, but are there certain risk factors for the development of pelvic organ prolapse?
A. Well, some of it is generic, which we don't have full elucidation of those ideas or

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terms. Certainly, other risk factors are smoking; people who have had vaginal deliveries as

opposed to C-sections; people who have connective tissue disorders, that can lead to it; people who are sort of prone to chronic conditions, such as coughing, straining; people with job environments that lead to a lot of heavy lifting that are on their feet a lot; people who are parachute jumpers, things that are high-impact activities.
Q. Did you mention childbirth?
A. I believe that I did.
Q. Okay.
A. But if I didn't, then, yes.
Q. Okay. And increasing age?
A. Increasing age, well, prolapse does increase with age. Whether or not that's necessarily a true risk factor or not, it's hard to truly say.
Q. What are the nonsurgical treatments -- treatment options for pelvic organ prolapse?
A. So nonsurgical treatments include observation, exercise therapy, trying to improve your core muscles, trying to improve the pelvic floor tone. Utilization of pessary management.

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And those are about the limits to the nonsurgical treatments.
Q. Okay. What type of exercises provide nonsurgical treatment?
A. Typically, what one is trying to do is improve the levator muscles, which are the muscles surrounding the pelvic floor that help hold up the bladder, the vaginal area and the uterus, trying to identify those muscles first and then increasing the tone and strength over time. It usually takes, oftentimes, six to eight weeks just to improve upon that area.
Q. Okay. Is that an effective option for most women?
A. It's certainly a good option to start with, depending on their degree. If someone comes in with a Stage III prolapse, the chances of just behavioral therapy and pelvic floor physiotherapy to actually improve that are probably less than 10 percent.
Q. Okay. And you mentioned pessary. Can you explain what a pessary is?
A. So pessary is a silicone vaginal device made of many different styles and shapes specially fitted for the female based on their prolapse,

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whether it's the anterior, apical or posterior prolapse. It's oftentimes placed within the vaginal area.
Women have the ability to take it out themselves and self-care for it or they can come back periodically to have it taken out, cleansed

and then replaced.
Q. Okay. And what purpose does the pessary serve?
A. The whole goal of it is trying to improve the overall symptoms. It's basically symptom management that you're trying to improve. So if someone is symptomatic enough that they are wanting to do something about it and behavioral therapy is not working, pessary therapy is the first option.
Q. Okay. Does the -- the pessary, upon being placed within the vagina, does that provide support for the prolapsed organ?
A. Correct. It's a -- it's an internal strut, an internal area that's taking up space and has the prolapsed organ or the anterior, posterior, apical will not be allowed to protrude through the vaginal opening, basically, obstructing that area.
Q. Is pessary a good option for most

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women?
A. It's an option that's a personal choice. There are many, many women who do not want to have any type of vaginal device in place for a variety of reasons.
Q. What are some of those reasons?
A. Some of it is there's a generational gap. There's a lot of women who went through, in the older patient, who has never been exposed to a vaginal tampon; and so, culturally, they're just not used to putting anything within the vaginal area.
There are many women who were then in the era of vaginal tampons, where they were concerned regarding retained devices and have infections develop. And so, psychologically, they're concerned about something that's within that area for a period of time.
There are some women who have pelvic pain discomfort and just don't want anything in the vaginal area. There are patients who have urogenital atrophy and sort of narrow vaginal introitus and, consequently, can't tolerate that.
So there are many factors, many reasons.
Q. And are there -- does the patient who

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uses a pessary have any maintenance, chores associated with that?
A. Correct. So our recommendations are initially to be able to -- once it's put in place, patients will come back fairly soon within a two- to three-week period. We'll re-evaluate the tissues to make sure they're in good health and hygiene.
If they're in good health and hygiene, they either have the options to be able to do

self-care, self-cleansing of the device, which we educate them about. If they don't want to proceed along that, then we will follow them back up on a routine schedule, typically, within a three-month period and then extend it out, if their tissues continue to be doing well.
Q. Okay. And how often would a patient need to clean the pessary?
A. Well, it's very individualized also. So there are some ladies who are more factitious that would like to take it in and out themselves daily, cleanse it and put it in. There's other patients who may not have hand dexterity, who would prefer just not to know about it. So those patients we typically would see at the one month.

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If they're doing well, then we would see them at three months. If their tissues are doing well, then probably move it out to six months.
Q. And, Doctor, what are the surgical treatment options for pelvic organ prolapse?
A. So there are -- the emphasis of surgical treatment is basically to reduce the prolapse, to provide support. So there are a variety of treatments that are available. It depends on the compartment that you're talking about.
So on the anterior compartment, if you have a urethrocele, you can -- or, in general, I should say -- in general, you can have native tissue repairs. You can have augmented tissue repairs with graph materials are the two main types.
Q. And when you refer to native tissue repair, native tissue surgery, can you describe how that proceeds?
A. So native tissue repair is basically using suture material that's absorbable to plicate or buttress the prolapse.
Q. All right. So is that taking -- suturing the patient's own tissue to provide

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support?
A. So it's utilizing prolapsed tissue and sort of mending it, sort of plicating -- so typically it's -- say, I'll have an analogy to tailoring. You buy a suit, it doesn't quite fit. You need it tailored. And, in essence, they are basically taking that material and they're sort of buttressing it or tightening it up.
Q. Okay. And can that native tissue repair be done transvaginally and abdominally?
A. So, typically, it's done vaginally. So

there are vaginal approaches and abdominal approaches from the -- and, once again, it depends on the compartment you're talking about. Q. So is native tissue repair always a good option for your patients? A. Native tissue repair is -- is a good option if they have -- don't have a lot of associated risk factors to it. I think when we're talking to patients about the treatment choices, you're also talking about what the expected results are. We do know from historical data that native tissue repair in the anterior compartment has a 40 percent failure rate over time. If we're 39 trying to improve upon that, some of the treatments have been using grafted material to improve upon that area to improve the success rates as far as longevity.	38:23 to 39:4 FRE 403 Non-responsive	
mk070214, (Pages 39:11 to 57:2) 39 Q. Doctor, you mentioned that the native tissue repair is typically done transvaginally. What do you mean by -- by that, the approach? Can you describe what transvaginally means? A. Well, there are typically two approaches to pelvic prolapse reconstruction. There's vaginal approaches and there's also abdominal approaches. So from a vaginal approach, you can treat the anterior compartment. You can oftentimes treat the vault. You can also treat the posterior compartment. From the abdominal approach, you predominantly are treating the apical compartment with possibility with highly skilled treating a paravaginal defect anteriorly. 40 Q. Okay. So the transabdominal approach would require an incision into the abdomen? A. Typically, it's either done with an incision in the abdomen versus laparoscopy. Q. Okay. Would you consider the abdominal approach a more invasive procedure than a transvaginal approach? A. Certainly, if you're making an incision, correct. Q. Okay. And why is that? A. You're cutting through abdominal fascia, abdominal muscles, and when you're having to resew that back together, that's typically a six-week recovery period as opposed to a vaginal approach that is normally an outpatient or just an observation procedure, which patients get back to doing their sort of normal daily activities without		

pain, discomfort. Q. And are there additional risks associated with a transabdominal approach that are not present with a transvaginal approach? A. Typically, the risks are wound infection. The other risks are longer operation, so length of time under anesthesia. The risk of DVT -- DVTs are also a matter of length of time 41 from surgery. The issues of bowel dysfunction, going into the intra-abdominal area, so an ileus with possible secondary bowel obstruction are possibilities. Q. All right. And you mentioned the recurrence rate for a native tissue repair. Strike that. How would you describe the recurrence rate for a native tissue repair versus a graft-type surgery? A. Well, there are two types of grafts. There are biological grafts and there are synthetic grafts. So in regards to native tissue repair, oftentimes, you're using defective tissue that has the possibility of recurring on its own, and that's why the 40 percent tends to recur. When you're using biological grafts, they can be made of either porcine dermis, they can be made of bovine dermis. They also can be made of human cadaveric fascia. So how the body wants to respond to these materials, whether they will autolyze the material, whether your sutures will pull through the material, and then, hence, have a weakening of the repair is kind of up to how the body will respond. 42 The other alternative is using synthetic material, which instead of relying on an interpositional graft, the synthetic material actually acts as a true support where the body will then integrate within that material to provide support. Q. Okay. And you're referring to the polypropylene mesh? A. Correct. Q. Okay. Just getting back to the native tissue repair for a second, does the quality of the patient's tissue play a role in recurrence? A. Certainly, if people have poor tissue quality, if they have smoking history, if they have genetic factors, if they've had prior repairs in the past; in addition, if they've had an apical component, that is, apical prolapse component, that all leads to the possibilities of recurrence. Q. Now, you started to talk about the	42:10-42:18 FRE 401, 403 Irrelevant as there is no evidence of poor tissue quality in Plaintiff	

polypropylene mesh grafts. Can you generally describe the surgery for us?
A. For which compartment?
Q. Which compartment did you -- did you operate on Ms. Carlson?
A. So in Ms. Carlson, the compartment that

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we operated on was level 1 support, which would be the apical, in addition to the anterior compartment.
Q. Okay. Can you describe that type of vaginal mesh procedure?
A. So for Ms. Carlson we used the Uphold vaginal mesh support, in addition to the anterior colporrhaphy. So if you want it, the description is detailed in the operative report.
Q. Just generally, Doctor, if you could.
A. In general, it's utilizing support from the sacrospinous ligaments bilaterally to provide fixation to elevate the apical vault, which in her case would be the cervix, in addition to elevate the anterior wall to provide a good support structure, for which then the anterior colporrhaphy would reinforce that.
Q. Okay. So, basically, you're inserting a mesh material transvaginally, correct?
A. Correct.
Q. And that mesh material forms a graft or a support for the prolapsed organs; is that fair?
A. In her particular case, the Uphold device is really a strap, it's a polypropylene strap that is supporting her apex, which would be

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her cervix and vault. And that strap gets secured to the bilateral sacrospinous ligaments. The actual mesh that you may be referring to is probably not a great support, meaning it is not a full coverage of the anterior vaginal wall. It is a small platform.
Q. Okay.
A. The product that --
Q. You said that the body, I think you said integrates with -- with the mesh; is that right?
A. Correct.
Q. What did you mean by that?
A. When you're talking about a biological material, it's really an interpositional graft. So it is you're totally relying on your repair that the actual graft material itself and the sutures that are connected to it and the sutures then connect to a fixation point. If any of those areas -- much like a

trampoline -- if any of those areas break, whether the material fabric breaks, whether the suture breaks, whether the fixation point breaks, your repair has failed. It will come right back down because there's no integration of the natural

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tissues around that area to secure it in place, as opposed to a synthetic mesh material, that material is designed that as it's put in place, it is allowing the body to actually integrate within the material to be able to improve its strength over time.
Q. So the -- the patient's tissue actually has in-growth with the mesh; is that what you're saying?
A. Correct, it integrates within it.
Q. Okay. So is vaginal placement of mesh a good option for some patients with pelvic organ prolapse?
A. Absolutely.
Q. Why is that?
A. For the right patient for the right indications, it is one of the only options that are available for some patients to provide improved support and also relieving their symptoms.
Q. And are there benefits to placing the mesh through the vagina as opposed to through the abdomen?
A. Once again, depending on the compartment you're talking about, there are some areas, specifically the anterior or the posterior

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vaginal wall, that you cannot really place synthetic mesh from the abdominal approach. The abdominal approach is predominantly used for the apex.
But to your point, there are clear advantages from the vaginal placement as opposed to abdominal. We've elucidated those some in the past. Some of it is convenience for the patient, time in the operating room, blood loss, decreasing risk of bowel, postoperative issues, decreasing risk of DVT.
Q. Does the shape of the mesh that you place differ depending on the organ that's prolapsed?
A. Correct.
Q. Why is that?
A. Once again, you're trying to tailor it to the defect that's there. Everyone's body is a little bit different. There's no sort of one size that fits all. And so you, oftentimes, do have to tailor and shape it. The anterior compartment is a wider compartment, whereas, the posterior

compartment doesn't have as much width to require support. Q. How long has transvaginal placement of 47 mesh been an accepted part of medical practice to repair pelvic organ prolapse? A. I believe -- I believe the FDA first approved transvaginal mesh in 2004, but I could be wrong. Q. How long has it been a part of your medical practice? A. Well, I've been utilizing -- if you're including stress urinary incontinence, utilizing polypropylene mesh for slings, probably since 2000. Q. Okay. And how long have you been using mesh for pelvic organ prolapse repair? A. Are you including biological materials or synthetic material? Q. The polypropylene, synthetic? A. So polypropylene, I don't know the exact date. Q. Do you know about how many years you've been doing that? A. Probably since 2007. Q. And, Doctor, what's a sacral colpopexy? A. So sacral colpopexy is a procedure where synthetic material is used that's securing the apex of the vagina to the sacrum. Q. And is that performed using the same 48 synthetic mesh that we've been talking about? A. It's -- correct. It's used polypropylene mesh. Q. And that's -- is that an abdominal approach? A. Correct. Q. Okay. Is it good for physicians like yourself to have different options for their patients with pelvic organ prolapse? A. Yes. Q. Why is that? A. Because oftentimes during the preop evaluation, what you see in the office is different than what you see in the operating room. So you may, once again, depending on the patient's core muscles, depending on their anxiety level, being disrobed and undergoing a pelvic exam, depending on their time of day, whether it's early morning versus late in the afternoon, you may identify prolapse, which you can see. However, when you get under anesthesia, when your body is totally relaxed, all of a sudden you'll find other compartments that are relaxed. Q. And have the surgical options for pelvic organ prolapse changed over the last ten	46:25-47:5 FRE 403 Irrelevant as FDA info has been ruled inadmissible 47:6-10 FRE 401; 403 Irrelevant 47:21-48:6 FRE 401; 403 Irrelevant	

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years?
A. In general, surgical options have not.
Techniques and devices have changed.
Q. Okay. And how have the techniques
changed?
A. So traditionally from a vaginal
approach, if you're talking about anterior
compartment, in addition to native tissue repairs,
when biological grafts came into play, that would
kind of be the aspect. And then -- if you're
talking about apical repairs, we'd typically be
doing sacrospinous vaginal vault suspensions or
iliococcygeal vaginal vault suspensions.
Posteriorly, the same native tissue
repairs, grafted-type repairs. As things evolved,
a lot of patients -- a lot of surgeons did not know
the anatomy and didn't have the techniques to do
some of the more complicated sacrospinous ligament
repairs, iliococcygeal repairs with the
technique -- with the devices of the day. With
advances in devices for suture capturing devices
for advances in placement, it became easier for
surgeons to get to learn some of these operations.
Technology then changed to use
trocar-based systems. And then after that

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iteration, then it came back to sort of
site-specific-type repairs.
Q. What are trocars, Doctor?
A. So trocars are needles with cannulas
that are passed through tissue to try to get to a
certain area through a percutaneous or a puncture
type of approach.
Q. Okay. And were trocars used in
transobturator approaches?
A. For?
Q. For pelvic floor surgery?
A. Well, there are -- there are some
procedures or devices that were transobturator and
percutaneous approaches.
Q. Has there been a movement away from the
transobturator approaches?
A. Correct.
Q. Okay. And has there been a movement
away from the use of trocars?
A. I would say the majority of physicians
have. There are some who still believe that the
trocar-based systems are the best systems in their
hand.
Q. And you mentioned suture capturing
devices. Does the Uphold use a suture capturing

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device?

A. Correct. Q. Do you know what that's called? A. A Capio device. Q. Does the Uphold kit have trocars? A. No. Q. Okay. Is there -- do you believe there's advantages to the Capio device over trocars? A. Absolutely. Q. What are those? A. The key advantage is that you actually know exactly where you're placing it based on digital palpation, digital feel. You are utilizing the device as it's being deployed into the position and location that is desired. With a trocar-based system, it is a nonpalpatory pass that is based on your intellectual judgment and 3-D dimensional imaging of the pelvis and structures around the area. Q. Okay. And when you say a pass, that's the piercing of the tissue? A. That's the trocar movement through the tissues. Q. Okay. And so if you can't digitally 52 palpate where you're placing that, does that create risks for the patient? A. Correct. Q. And what kind of risks are associated with the trocar that are not associated as much with the Capio? A. It probably depends on the patient's anatomy and it depends on the surgeon's skill and -- Q. Let me ask it a different way then. Why is it an advantage to be able to digitally palpate or feel where you're placing the sutures? A. In my hands, I much prefer to be able to palpate the structures that I know, which would include the ischial spine, the sacrospinous ligament, and once palpating these structures that are identifiable, utilizing a device or a suture technique to place it in that as opposed to relying on something that I have no actual palpatory feel. Q. Is there -- there a risk when you're using the trocar where you can't palpate where you're placing it? Is there a risk that you might perforate an organ? A. There's always a risk, you know, based 53 on any type of, you know, sharp device. Q. In terms of -- you mentioned an	53:2-21	

evolution of the devices over the past ten years as well, and you touched on the Capio. What about the size of the mesh itself, has that changed? A. It has. Q. And how has it changed? A. Originally, when synthetic material you're talking about, when it first came out, there were large sheets of synthetic material, also the weight and diameter of the mesh material, the stiffness of the mesh material was very heavy. It was thought that due to prolapse, intuitively, you'd need strong material. However, over time, as the science has evolved with the mesh technology, they have realized that a lighter weight, less dense mesh material would be better. They also realized that trying to place incisions away from the mesh material would be better. Utilizing less mesh, less tension would all be advantageous. Q. Why -- why is lighter or smaller mesh advantageous? A. Well, for -- I think those are two separate things. So lightweight mesh has more 54 pliability, less stiffness. It has more comfort for the patient, if you -- the other comment you said was less mesh. I think less mesh leads to less mesh being exposed at the incision line. Q. And so are there -- are there risks of exposure, erosion reduced in that -- that sense? A. I don't -- for -- certainly, there's less risk of exposure with less mesh material. Q. Doctor, do you still use synthetic polypropylene mesh today in some of your patients to treat pelvic organ prolapse? A. Yes. Q. Do you use it placed through the abdomen or only transvaginally? A. Both. Q. Both. And do you also use the polypropylene mesh slings to treat stress urinary incontinence? A. Yes. Q. Okay. That's the same mesh in both those products? A. Correct. Q. Do you find polypropylene mesh slings to be a safe and effective treatment for stress urinary incontinence? 55 A. Yes. Q. And in your experience, Doctor, is the	FRE 401; 403 Irrelevant 54:16-55:1 FRE 401; 403 Irrelevant; FRE 703 Foundation 55:5-12 FRE	

synthetic polypropylene mesh a safe and effective treatment for your patients with pelvic organ prolapse? THE WITNESS: For the right patient, yes. BY MR. SULLIVAN: Q. Okay. And for the right patient, Doctor, do you believe the Uphold product to be a safe and effective option for treatment of pelvic organ prolapse? A. Yes. BY MR. SULLIVAN: Q. Doctor, what are the -- strike that. Are there risks in utilizing vaginal mesh for the treatment of pelvic organ prolapse? A. Correct. 56 Q. What are those major risks? A. The risks are the same as native tissue repair, which would include bleeding, infection, injury to surrounding structures. With any surgery, the risk of anesthesia, DVTs. The only risk that is separate from the synthetic-based repair versus a native tissue repair is exposure of mesh material. Q. When you say exposure of mesh material, what is that? A. It's where the material may be seen within the vaginal wall. Q. Is exposure different from erosion? A. Correct. Q. What's erosion? A. Erosion would be where it is penetrating into another organ. Q. How did you become aware of these risks, Doctor? A. I think with any surgery, risks are incurred, and a lot of times from, you know, other surgeries, experience, training, you try to identify these risks and try to mitigate them. Q. Okay. So it's part -- was it part of your medical training as a urologist? 57 A. As within urology or within general surgery.	703 Foundation 55:14-19 FRE 703 Foundation	*Counter Designation to 55:21 – 57:2* *mk070214, (Pages 168:8 to 168:12)* *168* *Q. Are you aware that the Uphold product had no clinical testing before it was released onto the market?* *MR. SULLIVAN: Objection.* *THE WITNESS: I was not aware of that.*
mk070214, (Pages 58:18 to 59:21) 58 Q. Are you familiar with directions for use that accompany the Uphold product? A. Yes.		*mk070214, (Pages 166:4 to 168:1)* *166* *Did you know that the*

Q. Were you familiar with the directions for use that accompanied the Uphold product prior to your surgery on Ms. Carlson? A. Yes. Q. And you reviewed that before performing 59 an Uphold surgery for the first time? A. Yes. Q. Is that good practice to review the directions for use before using a medical device? A. Yes. Q. Why is that? A. There's important information within the instructions for use. It tells the precautions. It tells the description of the procedure. It tells the contraindications. Q. And is part of the reason you do that so that you can have informed -- informed discussion with your patient about the potential risks and complications? A. That may be a -- a part of it. Q. Okay. A. But I think for good medical care when utilizing a device, try to get as much information on it prior to use is important. Q. So that you are informed? A. Correct.	59:11-59:15 FRE 401, 403 Irrelevant	*manufacturers of the resin used in Boston Scientific Corporation's polypropylene mesh, which was included in their mesh kits, warned Boston Scientific, quote, medical application caution, do not use this Chevron Phillips chemical material in medical applications involving permanent implantation in the human body or permanent contact with internal bodily fluids or tissue?* *MR. SULLIVAN: Objection.* *THE WITNESS: I subsequently have known that information.* *BY MR. FABRY:* *Q. Okay.* *A. But at the time in 2010, I didn't know that information.* *(Kennelly Exhibit 19, Material Safety Data Sheet for Marlex Polypropylene (All Grades), was marked for identification.)* *BY MR. FABRY:* *Q. Let me hand you what I've marked as Exhibit 19. What's the revision date on that, on* *167* *the bottom highlighted?* *A. 10/9/2007.* *Q. And the other highlighted section there, the medical application caution, did I read that correctly?* *A. Correct.* *Q. And that's information that Boston Scientific did not provide to you in 2007, '8, '9 or 2010 before you implanted Ms. Carlson with a Boston Scientific mesh?* *A. Correct.* *Q. Are you familiar with the term clinical study with respect to medical*

		devices? *A. Yes.* *Q. And what, in your own words, is a* *clinical study?* *A. A clinical study would be the -- the* *use of either a device or a product or a chemical* *in humans, and then assessing its outcome.* *Q. Have you as a physician participated in* *any clinical studies?* *A. Yes.* *Q. And how important is clinical testing* *to you as a practicing physician when utilizing a* *new product on the market?* *168* *A. I think it's -- it's very helpful.*
mk070214, (Pages 61:14 to 61:17) 61 Q. Are you aware of any of your patients on whom you've implanted the Uphold product that have complained or presented with mesh exposure? A. Not that I recall.	61:14-17 FRE 401;403 Misleading: implies no patients had problems and witness cannot make that representation without 100% follow up of all patients.	
mk070214, (Pages 61:23 to 66:5) 61 Q. Is one of the risks of pelvic organ prolapse repair using the vaginal mesh that it will not result in a complete resolution of the woman's 62 prolapse? A. With any surgery, there's a possibility of incomplete support or recurrence. Q. Okay. Why is that? A. It's just the nature of the process itself. There's many factors underlying tissue, patient body habitus. Q. One of the risks associated with vaginal mesh for treatment of pelvic organ prolapse is pain; is that correct? A. As with any surgical procedure. Q. Why is that?		

A. Pain is in the eye of the beholder. So it's a subjective response for which there are no definitive tests that identify the exact location, pinpoint triggers for pain. Q. Getting back to the risk of exposure for a second. Are you aware of any factors that increase the risk of exposure in a patient? A. So from vaginal surgery, the risks are placing the mesh over the incision area, performing a hysterectomy at the same time, smoking, excessive bleeding at the time are wound-healing issues. Q. And is one of the risks associated with vaginal mesh surgery for the treatment of pelvic 63 organ prolapse urinary incontinence? A. For people who have Stage III or IV prolapse or called stress incontinence can occur. Q. And do you know why that is? A. Typically, if there's a significant prolapse, the prolapse itself is supporting the urethra. So once you reduce the prolapse, the urethra becomes unsupported and then you have occult stress incontinence. Q. Back in July of 2010, which was the month that you performed the Uphold surgery on Ms. Carlson, did you have a practice as to your informed consent procedure with a patient undergoing that type of surgery? A. Correct. Q. And what was your procedure at that time? A. So the process -- and informed consent is a process, so it's more than one encounter. So it's going through the understanding of what is the underlying problem at hand; identifying the condition; explaining the different options available; trying to provide reasonable expectation of outcomes; and then reviewing the associated risks alongside the treatment. 64 Q. And do you typically tell your surgical patients about the likelihood or the chance of having a particular complication? THE WITNESS: We inform patients of the potential complications that can arise. BY MR. SULLIVAN: Q. Back in July of 2010, was it your practice to give patients a likelihood of success or a likelihood of the occurrence of any particular risk? A. In regards to success, we typically try to give them success of either good, fair or poor. Q. Okay. What about with respect to the	63:10-64:7 FRE 401; 403 Irrelevant	

likelihood of an occurrence of any complication, a particular complication? A. I don't use percentages. Q. And why is that? A. Percentages change with each and every surgery you do as far as the denominator. So if you're going to track your own personal percentages or you're going to use national percentages or other percentages, it's not really -- you have to choose what is the best area. 65 So I think it's -- it's best in your hands with also understanding that things that are in your hands, other things may occur. So that's why you still have to give not just your experience, but what in general is out there, what may potentially happen. Q. Okay. So back in July of 2010, was it your practice to give patients your personal experience in terms of outcomes for the Uphold procedure? A. It's a combination of personal experience, in addition to national experience that's been out there. Q. And how do you know the national experience at that time? A. The national experience is what has been written in the instructions for use, but it's been written in the medical literature, discussion with colleagues regarding these type of procedures. Q. And it was your practice to share all that with patients back in July 2010 prior to performing the surgery? A. Yes, and even prior to that because we consented her twice. Q. Okay. And we'll get to those forms in 66 a minute, Doctor. Doctor, is there any treatment for pelvic organ prolapse that is a guaranteed hundred percent cure? A. No.	64:15-66:1 FRE 401, 403 Irrelevant	
mk070214, (Pages 67:4 to 73:23) 67 Q. So, Doctor, I'm handing you a multipage document that we've marked as Exhibit Number 16 for your deposition. Do you recognize that, Doctor, as the directions for use for the Uphold product? A. Yes. Q. And this is the -- a document that you said you were familiar with, correct? A. Correct. Q. And you reviewed this -- these directions for use prior to performing the surgery		

on Ms. Carlson back in July of 2010, correct?
A. Correct.
Q. And you're aware the -- this -- these directions for use accompany the Uphold product?
A. The company is Boston Scientific.
Q. They accompany -- they come with the product?
A. Yes.
Q. Okay. And did you review the directions for use from out of the product packaging or on line or how did you obtain them to

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review them?
A. I obtained it prior to my even considering utilizing the Uphold product in any patient.
Q. And how did you obtain them?
A. By obtaining training at a Boston Scientific educational cadaveric lab.
Q. Okay. And when did you attend that lab?
A. Prior to -- I don't know exactly. Probably in 2009.
Q. Okay. How many of those trainings have you attended that have been put on by Boston Scientific?
A. I don't know the exact number, but more than four and less than ten.
Q. All right. And were you a trainee in all those four to ten?
A. No.
Q. Okay. How many did you attend as a trainee where you were a student, if you will, at those trainings?
A. I don't recall exactly; but, obviously, the first ones that I went to was a trainee and student.

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Q. Okay. And then did you -- were you on the faculty or did you teach some of those trainings as well?
A. Correct.
Q. Do you know how many you've taught?
A. I believe in 2011, there were two of them.
Q. Did you teach any in any other years?
A. I -- I don't know. My records, I don't have.
Q. Could you describe the trainings that you attended as a trainee?
A. As a trainee, it was a multi-day session that involved several didactic lectures; involved several presentations; reviewing then

underlying anatomy; reviewing the different compartments with the different treatments; getting hands-on knowledge, in addition to ability to use the products to become familiar with the device, with the technique; and then applying that skill on cadavers under professionals who had utilized the therapy and the device and could offer their suggestions, tips, tricks as far as to how to improve outcomes for patients. Q. Okay. Did you find those trainings 70 valuable? A. Absolutely. Q. The -- do you know who taught at the seminars that you attended as a trainee? A. The -- I don't recall. There are multiple physicians because, remember, pelvic organ prolapse and urinary incontinence are several conditions. So there are some conditions that are treated for stress urinary incontinence, of which there are a variety of techniques, variety of methods; there's techniques that are used for anterior compartment, apical compartment and posterior compartment. And so they had a variety of surgeons who were skillful at those different areas. Q. Do you know which Boston Scientific products you received that training on? A. For the multiple -- like the daily sessions, the products at that time were Pinnacle, Uphold, the slings, which included Advantage Fit, the Solyx, and I believe at the time they also had Durasphere. Q. So getting back to the directions for use that we've marked as Exhibit Number -- what is it, Doctor, 16? 71 A. Correct. Q. Doctor, do you have an understanding that the FDA reviews and clears the language in directions for use? A. Correct. Q. And you understand and have testified the directions for use provide information about how to use the Uphold device, correct? A. Yes. Q. And they provide information on the risks associated with the use of the product? A. Correct. Q. If you'll turn to the third page of the directions for use, Doctor. Up in the first column on the left, do you see where it begins, training on the use of the Uphold vaginal support system? A. Yes.	71:1-5 FRE 403 Irrelevant as FDA info has been ruled inadmissible	*Counter Designation to 71:13 - 73:23* *mk070214, (Pages 170:7 to 171:17)* *170* *Q. We talked a little bit about your*

Q. And it says, training on the use of the Uphold vaginal support system is recommended and available. Contact your company's sales representative to arrange for this training. Physicians should have experience in the management of complications resulting from procedures using surgical mesh. Did I read that correctly?

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A. Yes.
Q. And that training that's referred to in that paragraph, that's the training you were just describing that you attended?
A. Correct.
Q. And did you attend that training on the Uphold product prior to your surgery on Ms. Carlson in July of 2010?
A. Yes.
Q. Where was the training that you attended, if you remember, on the Uphold product?
A. I don't recall.
Q. Okay. All right. The next paragraph, Doctor, says, the safety and effectiveness of the Uphold vaginal support system compared to conventional surgical repair for pelvic organ prolapse have not been demonstrated in randomized controlled clinical trials. In the United States, substantial equivalence of the Uphold vaginal support system to synthetic mesh has been demonstrated through benchtop testing. Did I read that correctly?
A. Correct.
Q. And having reviewed directions for use prior to your surgery on Ms. Carlson, you were

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aware of that paragraph?
A. Yes.
Q. In addition to the training you received from Boston Scientific, did you receive other training in implanting of vaginal mesh for the treatment of pelvic organ prolapse?
A. Yes.
Q. Can you describe what that training or where you received that training?
A. I received the training on a variety of different products over the years. So in regards to Ethicon, I received training regarding their Prolift procedure. Received training on the TVT Secur. Received training on the TVT-ABBREVO. In regards to American Medical Systems, I've received training on all of their products also. In regards to Bard, I received training on all of their products also. In regards to Coloplast, I've received training on all their

interaction with Boston Scientific's sales representatives. Did any sales representatives talk to you about removal of the mesh if there's a problem?
A. I don't specifically recall.
Q. Did any Boston Scientific sales representatives tell you before or discuss with you before Martha Carlson was implanted in 2010 the fact that the mesh may be impossible to remove once implanted?
A. I don't recall them stating impossible.
Q. Did they -- any Boston Scientific sales representatives tell you before you implanted Martha Carlson that the removal process is tedious, it includes cutting the mesh scaffold from healthy tissue without causing damage?
MR. SULLIVAN: Objection.
THE WITNESS: I don't recall.

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BY MR. FABRY:
Q. However, in -- when was your article on use of lasers to remove mesh written?
A. This was accepted February 23rd, 2012.
Q. And by 2012, you had figured out that the removal of mesh is a tedious process that includes cutting the mesh scaffold from healthy tissue without causing damage?
A. Correct.
Q. And did any of the Boston Scientific sales representatives that you talked with before you implanted Martha Carlson in 2010 ever tell you that pain can persist even after the mesh is removed?
A. I don't recall.

products. Q. And when you say all of their products, you're referring to vaginal mesh products? A. Correct.		*Q. Is that something you're aware of now?* *A. Yes.*
mk070214, (Pages 76:19 to 80:24) 76 Q. And on Page 4, the second bullet point on the upper left column says, like all foreign bodies, a mesh may potentiate an existing infection reaction or sepsis. Do you see that? A. Yes. Q. Then the next one is tissue responses 77 to the implant could include local irritation of the wound site, vaginal erosion or exposure through the urethra or other surrounding tissue, migration of the device from desired location, fistula formation, foreign body reaction and inflammation. The occurrence of these responses may require removal or revision of the mesh. Do you see that? A. Yes. Q. Were you aware of that, Doctor, back in July 2010 when you performed the surgery on Ms. Carlson? A. Yes. Q. And the next bullet point, Doctor, says, mild to moderate incontinence may occur due to complete support. Were you aware of that as well? A. I'm aware that occult stress incontinence may occur. Q. And you were aware of that at the time you performed the surgery? A. Yes. Q. And skipping down one bullet, it says, known risks of surgical procedures for the treatment of prolapse include pain, infection, 78 erosion/exposure, device migration, complete failure of the procedure resulting in recurrent or de novo prolapse and/or incontinence. Do you see that? A. That's the right-hand column listing the adverse events? Q. I'm looking at the left-hand column. It's the sixth bullet point down there. A. Oh, yes. Q. Do you see that? A. Yes. Q. Okay. Were you aware of those risks, Doctor, back when you were counseling Ms. Carlson on the Uphold procedure?	78:12-78:17 FRE 401, 403 Irrelevant,	

A. Those are known risks for any surgical procedure for prolapse, except the erosion exposure. Q. Okay. And you were aware of those back at that time, July 2010? A. Yes. Q. Okay. Then going down a little further, Doctor, under the heading Precautions. It says, surgical treatment of female pelvic organ prolapse should be performed by clinicians with adequate training and experience. 79 Do you see that? A. Yes. Q. And, Doctor, back in July 2010, did you consider yourself to have the requisite training and experience to perform the Uphold procedure? A. Yes. Q. Then turning to the adverse events, Doctor, which is the right-hand column on that page, it says, potential adverse reactions that may be associated with surgically implanted materials include, and there's a list of bullet points there with -- with those risks indicated, correct? A. Yes. Q. All right. And I don't have to hit them all, but the first one involves foreign body reaction; do you see that? A. Yes. Q. And if you go a little further down, there's dyspareunia? A. Yes. Q. What's dyspareunia, Doctor? A. Discomfort during sexual intercourse. Q. And the next one is erosion/extrusion? A. Yes. Q. And a little further down is 80 inflammation (acute or chronic)? A. Yes. Q. And then mesh and/or tissue contracture? A. Yes. Q. A little further down, pain, discomfort, irritation; do you see that? A. Yes. Q. And a little further down, recurrent prolapse; do you see that? A. Yes. Q. That means the prolapse returns at some point? A. Yes. Q. A little further down, urinary incontinence?	non-responsive	

17 A. Yes. 18 Q. A little further down, vessel/nerve 19 injury/perforation; do you see that? 20 A. Yes. 21 Q. And those are all risks that you were 22 aware of back in July 2010 before you performed the 23 surgery on Ms. Carlson, correct? 24 A. Yes.		
mk070214, (Pages 81:19 to 82:20) 81 19 Q. Doctor, how many other -- if you know, 20 how many other physicians have you trained on the 21 placement of mesh for the treatment of pelvic organ 22 prolapse? 23 A. I don't know exactly, but probably more 24 than 250. 25 Q. And were those all at Boston Scientific 82 1 Corporation trainings? 2 A. No. 3 Q. Where -- where -- where did you provide 4 those trainings to other physicians? 5 A. For Bard Urologic, American Medical 6 Systems, Coloplast, Ethicon, J&J and Boston 7 Scientific. 8 Q. And do you enjoy teaching those 9 seminars? 10 A. Correct. 11 Q. And why is that? 12 A. I think the value of sort of going into 13 medicine is constantly learning. And once you 14 become proficient at things, it's also the joy is 15 to train others to try to get the best out of their 16 abilities. In addition, it's trying to train 17 people so they can help other patients down the 18 line and avoid some of the pitfalls that have, you 19 know, happened prior to them learning new 20 techniques.	81:19-82:7 FRE 401; 403 Irrelevant	*mk070214, (Pages 82:21 to 82:23)* *82* *21 Q. Prior to your surgery on Ms. Carlson,* *22 do you know how many other physicians you trained?* *23 A. I don't know.*
mk070214, (Pages 82:24 to 85:6) 82 24 Q. Okay. Doctor, on Page 3, sorry, of the 25 directions for use, there's -- I skipped over the 83 1 paragraph that's headed Intended Use/Indications 2 for Use; do you see that? 3 A. Yes. 4 Q. Was your use of the Uphold with respect 5 to Ms. Carlson consistent with that intended use? 6 A. Yes. 7 Q. And, Doctor, did you in considering 8 whether to perform the Uphold surgery on 9 Ms. Carlson or considering all the available 10 treatment options for her, did you weigh the risks 11 set forth in the directions for use against the	84:24-85:6 FRE 401; 403 Relevance	

potential benefits to her? A. Knowing the information, instructions for use, knowing the patient's history and the associated prolapse and what we were trying to accomplish, the risks and benefits were weighed in decision to use the Uphold device. Q. And that was a decision you and Ms. Carlson arrived at together? A. As stated before, the challenge is that what you notice at the time of surgery may be different than what is seen in your preop area. In Ms. Carlson's case, she also had a gynecologist physician who we were working in conjunction, and the issues discussed at that time 84 were how are we going to treat her apical component, mainly her uterus. There was some discussion whether or not she was planning to have a hysterectomy. There was some discussion how much uterine prolapse there was. And so, consequently, the decision was at the time of surgery to decide whether or not she would absolutely need to have any type of hysterectomy, uterine suspension. Consequently, deciding what's happening to the uterus dictates the actual treatment that we're using, and given the intraoperative findings, given the patient's discussions prior to it, given her desire to maintain her uterus, that's when the Uphold was chosen at that time. Q. Okay. And you mentioned the plaintiff's -- I'm sorry -- Ms. Carlson's gynecologist. Do you recall that doctor's name? A. Dr. Stein. Q. If we could finish up for the directions for use, Doctor. Do you see on Page 4 there's discussion of the operational instructions? A. Yes. Q. And do you have any criticism of the operational instructions, Doctor, on the DFU? 85 A. I haven't gone through them in detail. Do you want me to? Q. No. Do you recall -- having reviewed them in the past, do you recall having any objections or criticisms of them? A. No.	84:24-85:16 FRE 401, 403 Irrelevant; Foundation, no present recollection as basis to offer opinion	
mk070214, (Pages 85:14 to 86:23) 85 Q. Doctor, I'm handing you a three-page document that we've marked as Exhibit Number 17. Are you familiar with that document, Doctor? A. I have seen this before, yes. Q. Okay. And if you'll tell us what that is.	85:14-86:23 FRE 403 Irrelevant because FDA info has been ruled	

A. This is a notification from the FDA, Food and Drug Administration, regarding a Public Health Notification regarding serious complications associated with transvaginal placement of surgical mesh in the repair of pelvic organ prolapse and stress urinary incontinence. 86 Q. Okay. Is this a document that you reviewed at or near the time it first was published by the FDA? A. I don't recall. Q. Do you see that under that bold print heading it has the issued date as October 20th, 2008? A. Correct. Q. And that was about a year and a half or so prior to your surgery on Ms. Carlson? A. Correct. Q. Do you know whether you saw this document before that surgery? A. I don't recall. Q. You said you're familiar with the document. You have reviewed it at some point? A. Yes. Q. And did the FDA notification that we are discussing, did that provide any new information to you in terms of the risks associated with pelvic organ prolapse mesh surgery? A. It did not provide any new associated risks.	inadmissible	
mk070214, (Pages 87:20 to 89:24) 87 Q. Let's look at Exhibit 17, which is the 2008 notification, Doctor. The second paragraph under Nature of the Problem, do you see it says, the most frequent complications include erosion through vaginal epithelium, infection, pain, urinary problems and 88 recurrence of prolapse and/or incontinence. There were also reports of bowel, bladder and blood vessel perforation during insertion. In some cases, vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia. Did I read that correctly? A. Yes. Q. All right. And are those complications that you were aware of back in July 2010 before you performed Ms. Carlson's surgery? A. Yes. Q. Under the recommendations provided here at the bottom of the page, it says, physicians	87:20-89:24 FRE 403 Irrelevant as FDA info has been ruled inadmissible	

should obtain specialized training for each mesh placement technique and be aware of its risks; do you see that? A. Yes. Q. And that's something you did, correct? A. Correct. Q. You did that before operating on Ms. Carlson, correct? A. Correct. Q. The next one is, be vigilant for potential adverse events from the mesh, especially 89 erosion and infection; is that correct? A. Yes. Q. And is that -- were you vigilant for such adverse events? A. Yes. Q. And is that one of the reasons you see patients postoperatively? A. Correct. Q. And did you see Ms. Carlson postoperatively? A. I did. Q. And were you vigilant during those postoperative visits for those conditions -- those adverse events? A. As with all events, yes. Q. The fourth bullet point says, Doctor, inform patients that implantation of surgical mesh is permanent, that some complications associated with the implanted mesh may require additional surgery that may or may not correct complication. Back in July 2010, Doctor, were you aware that implantation of the mesh was intended to be permanent? A. Yes.		
mk070214, (Pages 93:3 to 100:10) 93 Q. Doctor, I'd like to turn to your care and treatment of Ms. Carlson, and I see you have your records in front of you, and that's fine. You can refer to those if you need to. My first question is: When did you first have contact with Ms. Carlson? A. The first contact that I recall was my initial visit with her, which I -- according to my records, was on 4/26/10. Q. Now, Doctor, do you recall or do you have any record of performing urodynamics testing on Ms. Carlson prior to that date? A. Yeah. So I did interpret urodynamic testing done on her on 3/2/2009. Q. Okay. So let's start with that, if you could. Do you have that record?		

A. Yes.
Q. Okay. First of all, how was Ms. -- how did Ms. Carlson come to you? Was she referred?
A. Well, I'm a medical director for the Charlotte Incontinence Center, which is diagnostic testing facilities throughout the Charlotte area, and consequently, part of the services, we allow

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physicians in the community to be able to refer patients into the diagnostic testing area that then have the option of either getting the tests sent back to them so they can interpret or they can interp -- send it to one of their partners, or if they would like me to interpret it, I will do the interpretation, provide them a documentation and a interpretation.
Q. Okay. In this case, do you know who referred Ms. Carlson to you?
A. Dr. Stein.
Q. Okay. And that's the same Dr. Stein we spoke of earlier?
A. Correct.
Q. So she was Ms. Carlson's gynecologist?
A. Yes.
Q. All right. And do you know why Dr. Stein was referring Ms. Carlson to you for urodynamic testing or test interpretation?
A. She had a prolapsed bladder.
Q. What's -- what's the purpose of urodynamic testing then presentation?
A. The testing is to evaluate the lower urinary tract regarding filling sensation, looking for any detrusor activity, evaluating for occult

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stress incontinence and then assessing their voiding ability.
Q. And why is that something that's indicated in a patient with pelvic organ prolapse?
A. If they're planning on surgical repair and they're concerned that there may be occult stress incontinence, then you have to discuss the possibility of treating stress incontinence at the same time or informing the patient that they may have significant stress incontinence after surgery.
Q. And what were the results of Ms. Carlson's urodynamic testing?
A. So at that time, she had a normal bladder capacity of 520 CCs; intact bladder sensation; normal bladder compliance; there was no overt urodynamic detrusor activity; urge incontinence was not documented; stress incontinence was not documented, even with the prolapse reduced; there's no vesicoureteral reflux or bladder diverticulum; she had a Grade III

cystocele; she had normal to low normal detrusor voiding pressure with some abdominal strain effect and normal uroflow pattern with complete bladder emptying.
Q. Okay. So what did that tell you? Was

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there anything abnormal in those results?
A. She did have a Grade III cystocele, which would be abnormal.
Q. What about the detrusor voiding pressure, was that an abnormal finding, Number 9?
A. No, that's within normal to the low normal range.
Q. Okay. And so did you make any recommendations as a result of this test?
A. Yes.
Q. What were those recommendations?
A. So my addendum was this patient does indeed have pelvic organ prolapse and Grade III cystocele. The patient did not appear to have any signs of stress incontinence with her prolapse reduced. Correlation with clinical exam would be appropriate. If the patient is planning to undergo surgical therapy, does not appear as though stabilization of bladder neck is needed at this point in time. If you have any questions of the study or treatments, please don't hesitate to contact me.
Q. And just briefly, what's stress urinary incontinence?
A. So stress urinary incontinence is

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during exertional activity, increased abdominal pressure causes the urethra to expel urine.
Q. So it's urinary incontinence with things like coughing or sneezing or --
A. Correct.
Q. -- moving from sitting to standing, things like that?
A. Correct.
Q. And so you didn't find any signs of that, correct?
A. Correct.
Q. And so that wasn't something that would need to be repaired at the same time as the pelvic organ prolapse repair?
A. Based on the urodynamics.
Q. Okay. All right. And just to make sure we have it, the date of your -- your -- did you do the testing or you reviewed the test data?
A. I reviewed the test data.
Q. Okay. When did you do that?
A. I dictated the test on March 2nd, 2009.
Q. Okay. All right. And when was the

next time you had any involvement in Ms. Carlson's care?
A. The next time seeing her was on

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4/26/10.
Q. So about a year later?
A. Correct.
Q. Okay. And you have that report of that office visit in front of you, Doctor?
A. Yes.
Q. All right. And just looking at that report, the first thing it says is, initial consultation, new patient, history and physical, correct?
A. Yes.
Q. The reason for consult is pelvic organ prolapse, correct?
A. Yes.
Q. And the requesting physician is identified as Dr. Stein, correct?
A. Yes.
Q. What was the history that was -- Ms. Carlson provided to you at that visit?
A. At that point in time, she stated she had a history of worsening systematic pelvic prolapse with symptoms beginning in 2008 on a bothersome scale, ranged from one to ten; her symptoms rated six out of ten. She mainly complained of heaviness, fullness, tissue

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protrusion from the vaginal area. She found the pessary use to be very uncomfortable. She had been evaluated by Dr. Stein and felt she needed vaginal reconstruction to include hysterectomy, anterior prolapse repair, plus/minus sling. And she was interested in proceeding with pelvic prolapse repair.
Q. Okay. Did -- did you --
A. She had other symptoms also.
Q. Okay. Symptoms that she reported to you as part of her history?
A. Correct.
Q. Okay. What were those symptoms?
A. She was voiding every two to three hours, getting up one time at night. She had occasional urge -- urgency. She complained of needing to void when rising from a seated position. She denied any obstructive voiding symptoms. She denied stress or urgent incontinence. She does leak a small amount with change of position, transitional movements. She did not wear any pad protection. She did not have any urine leakage

with her pessary in place. She was complaining of vaginal pressure heaviness, tissue protrusion from the vaginal area, low back pain. She did use 100 digital manipulation with splinting to help her with voiding and bowel movements. She does not have any blood in her urine, dysuria, bladder infections, pyelonephritis, kidney stones. She does have some problems with constipation, painful bowel movements, and a feeling of incomplete evacuation. She was not using any laxatives or fecal incontinence. She was menopausal. She was not currently sexually active and denied any symptoms of female sexual dysfunction.		
mk070214, (Pages 100:22 to 102:7) 100 Q. Okay. So the first thing you note in your report about her history is that she has had worsening symptomatic pelvic organ prolapse and her symptoms had begun in 2008, correct? 101 A. Yes. Q. And then you refer to a bothersome scale. What is a bothersome scale? A. So, it's a very subjective patient response that they rate themselves how bothered they are based on their symptoms. One being -- zero being no bother, ten being the worst bother. Q. Okay. And she rated that six out of ten? A. Correct. Q. And the symptoms that she complained of, which of those symptoms do you attribute to the pelvic organ prolapse? A. After the exam, I would state the heaviness, the fullness, the tissue protruding from the vaginal area, those were definitively from the pelvic prolapse. Q. All right. And you make note that she found the pessary to be very uncomfortable, correct? A. Yes. Q. So that reflects that she had tried a pessary to deal with the pelvic organ prolapse before coming to you? A. Yes. 102 Q. That's your understanding of her history? A. Yes. Q. Okay. So when she presented to you, she was already wanting to have pelvic organ prolapse repair? A. Yes.		

mk070214, (Pages 102:19 to 119:25)

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Q. Did you speak with Dr. Stein after seeing Ms. Carlson this first visit?
A. Yes.
Q. Okay. And why did you -- why did you get in touch with Dr. Stein at that time?
A. Well, the patient thought that she needed a hysterectomy. Based on my evaluation and

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examination, I questioned whether a hysterectomy would be needed or not. So, consequently, we wanted her to meet with Dr. Stein again and discuss the actual needs for hysterectomy or not.
Q. Getting back to some of the symptoms she presented with, you made mention of occasional urinary urgency. Can you explain what urinary urgency is?
A. Urgency is the sensation to have to go to the rest room, whether bowel or bladder, that is more of an uncomfortable sensation.
Q. Okay. Feeling an urgent need to urinate?
A. Correct.
Q. All right. And you said she typically voids every two to three hours and nocturia once a night, and that means she gets up from sleep to go to the bathroom?
A. Yes.
Q. All right. Is -- is that voiding every two or three hours, is that a frequent frequency of urination?
A. It's very individualized, but in a 24-hour day that's voiding typically, you know, upwards 10 to 12 times a day, which would be more

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than normal.
Q. Okay. And you noted she had some low back pain. And you mentioned digital manipulation splinting. What is that?
A. Typically, when someone is trying to either empty their bowels or their bladder, if they have significant prolapse with things protruding, they feel as though they can't empty. So they will use their fingers to push on the prolapse to push it back inside the vaginal area or push on their peroneum to try to improve bladder emptying or bowel emptying.
Q. Okay. Okay. After taking Ms. Carlson's history, you examined her?
A. Yes.
Q. And what did you find in your examination on April 26th, 2010?
A. Specifically regarding sort of the GU exam, she had mild atrophic genitalia without any

ulcerations; her genital hiatus was 3 centimeters, her perineal body was 3 centimeters; her urethral meatus was in normal position without any caruncles or abscesses; the urethra was palpated and showed no significant periurethral scarring, diverticulum or tenderness; her urethrovesical junction was

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supported; the bladder was palpated showing prolapse; the anterior vaginal wall showed a Grade III cystocele with rugations at the bladder neck; loss of apical rugations; she has a central apical and paravaginal defect. Posteriorly, the vaginal wall showed a Grade II apical rectovaginal defect. With Valsalva straining, with the prolapse reduced, no stress incontinence was documented. In the standing position, with Valsalva straining, the cervix appeared to be supported; no significant uterine descensus. The Adnexa showed bimanual exam did not reveal any masses in the left or right paravaginal areas. Her cervix and uterus were intact without descensus. The anus and perineum were without excoriation or lesion.

Q. Okay. So you found she had a Grade III cystocele, correct?

A. Correct.

Q. And earlier I think you testified that the grading runs from, is it from I to IV?

A. Correct.

Q. Okay. So this was a more significant prolapse?

A. Correct. Outside the vaginal opening.

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Q. Okay. So the bladder was actually coming out the vaginal opening?

A. Correct.

Q. And you also noted a Grade II apical rectovaginal defect, correct?

A. Correct.

Q. And the -- is that a rectocele?

A. It's a high rectocele.

Q. Okay. And is Grade II a significant prolapse?

A. It's not outside the vaginal opening.

Q. Okay. Is it -- I'm sorry. Rectoceles graded I through IV as well?

A. Correct.

Q. Okay. Okay. And your diagnosis at that time is listed next to impression, correct?

A. Yes.

Q. And you noted, symptomatic pelvic organ prolapse, Grade III cystocele with apical and paravaginal defect. You noted Grade II rectocele mildly bothersome for the patient. How was the rectocele bothersome?

A. Getting back to whether or not she was using splinting, if she was having difficulty with her bowel movements.

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Q. All right. And then Number 4 you have, overactive bladder symptoms. What's overactive bladder?
A. So overactive bladder is a lower urinary tract symptoms of urgency, frequency, nocturia and/or urgent incontinence.
Q. Okay. And then Number 5 says, long discussion with patient today regarding the anatomy and physiology of the bladder function and the various treatment options for pelvic prolapse, overactive bladder and urinary incontinence. She was informed she will likely need interior prolapse repair with graft, plus or minus sling, depending on urodynamic testing.
Let me stop there for a second. Did you order updated urodynamic testing or were you sort of unaware at this point that it had been done a year prior?
A. I think in my -- let's see. I thought I recalled that she said she has had urodynamic testing. So as of the initial visit consultation, I did not have any documentation of her testing.
Q. Okay. But you interpreted her urodynamic testing about a year before?
A. Correct.

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Q. Okay. But you didn't have that handy is basically what the problem was?
A. Correct.
Q. And when you say, plus or minus sling, that refers to, for treatment of possible stress urinary incontinence, depending on the results of that testing?
A. Correct, whether or not she has occult stress incontinence with the prolapsed reduced.
Q. Okay. And when you refer to graft in that section, you're referring to synthetic or biological graft?
A. All of the above.
Q. All of the above. Okay.
Do you recall -- do you have an independent memory of this discussion with Ms. Carlson?
A. I do not.
Q. Do you know why you would have discussed overactive bladder with Ms. Carlson at that time?
A. Because oftentimes overactive bladder occurs without any type of pelvic prolapse; consequently, if you repair pelvic prolapse, the

overactive bladder symptoms may still persist. And

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so trying to get proper expectations prior to surgery improves the postoperative outcomes.
Q. Okay. All right. And I left out that this says you talked about overactive bladder and urinary incontinence. Was that sort of all in the same setting?
A. Correct. With urinary incontinence, you can have urgent incontinence, in addition to stress incontinence.
Q. In her case, she was having urgent incontinence or at least urgency?
A. She was having urgency.
Q. Although I think you said --
A. I think she had occasional leakage when she went from sitting to standing.
Q. Okay. So as part of your discussion with Ms. Carlson at this initial visit, one of the things you wanted to do was manage her expectations in terms of the overactive bladder symptoms and urinary urgency, frequency, nocturia?
A. Correct.
Q. All right. Further down in that same impression Number 5, you said, her symptoms are mainly overactive bladder. She will likely need regular plication, posterior -- and I can never say

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that word -- colporrhaphy?
A. Colporrhaphy.
Q. Colporrhaphy. What is colporrhaphy?
A. It's a native tissue repair of the posterior compartment.
Q. When you say she would likely need regular plication, what does that mean?
A. Native tissue repair plication of the posterior compartment, she will not need a graft.
Q. Okay. That was to deal with the rectocele?
A. Correct.
Q. All right. When you say her symptoms are mainly overactive bladder, why did you say that?
A. She was complaining of urgency, frequency, nocturia.
Q. Okay. And continuing on it says, the indications, alternatives, risks and benefits of vaginal reconstruction were reviewed in detail. She verbalized her understanding and wishes to proceed with surgery, all questions were answered. Did I read that correctly?
A. Correct.
Q. All right. Do you recall whether

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Ms. Carlson had specific questions? A. I don't recall. Q. Okay. Under plan, Number 2 says, schedule patient for anterior prolapse repair with graft, posterior colporrhaphy, coordinate surgery with Dr. Stein. Check with Dr. Stein to see if patient needs hysterectomy. When you say anterior prolapse repair with graft, are you referring to the cystocele repair? A. Correct. Q. Okay. When you use the word graft in that context, are you referring to synthetic graft? A. It's synthetic or biologic. Q. Okay. All right. So that's -- when do you make the determination of what course in -- in the care of a patient like this do you decide what type of graft to use? A. The main issue determines on what -- at the time of surgery what else is prolapsing. If you're trying to get apical support, which is for her case, then using an Uphold strap support system that's really elevating the apex and cervix is the key. If she did not have uterine descensus, then the options -- I wouldn't have used the Uphold		
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device. It was just truly a cystocele with paravaginal defect. Q. Okay. So that was the right product for her -- BY MR. SULLIVAN: Q. -- specific circumstances? THE WITNESS: Based on her -- based on her presentation, yes. BY MR SULLIVAN: Q. All right. Number 3, you said, brochures/information given to patient regarding pelvic prolapse; do you see that? A. Yes. Q. Do you recall what brochures or information you provided to her? A. We -- typically, we give the Krames pelvic organ prolapse booklet of contemporary that was at 2010. There are updated versions today. Often we give information on pelvic prolapse specific to materials that we use. Q. When you say specific to materials you use, what do you mean by that? A. There are -- telling patients that	112:3-10 FRE 611 Leading 112:12- 113:15 FRE 401, 403 Irrelevant	
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there are native tissue repairs, there are biologic		

repairs, there are synthetic repairs. We also have a handout that talks about the different types of surgical repairs, including anterior colporrhaphy, posterior colporrhaphy, sacral colpopexy, uterosacral vault suspension. Q. Based on this entry in the record, it says, brochures/information given to patient regarding pelvic prolapse. Do you know whether you provided brochures that discussed those procedures or just that -- A. The Krames brochure would be the definitive one that was given. As far as those two other documents, I do not recall. Q. All right. Number 4 in your plan, it says, dietary modification, pelvic physiotherapy; do you see that? A. Yes. Q. And can you tell me what -- what the plan was there, what you meant by that? A. So overactive bladder, one of the two behavioral treatments are dietary modification, avoiding coffee -- coffee, teas, colas, citrus products, acidity foods, nutritional things that 114 can irritate the urgency, frequency, nocturia. In regards to pelvic physiotherapy, urge suppression techniques, trying to improve the pelvic floor just in general will help overactive bladder and stress incontinence and has marginally support for pelvic prolapse, however, not for Stage III. Q. Okay. And Number 5, you said, patient was informed that overactive bladder symptoms will likely persist following pelvic reconstructive surgery, correct? A. Yes. Q. All right. It says, operative consent was obtained today emphasizing the enumerated risks, correct? A. Yes. Q. And when you -- when you note that, are you referring to a written informed consent form? A. Yes. Q. Okay. And we have as Exhibit Number 3 a document -- two-page document, looks like, with McKay Urology on the first page and says, Informed Consent for Repair of Pelvic Organ Prolapse; do you see that? Do you have that, Exhibit 3? Am I holding it? 115 A. Yeah, you're holding it. Yes, that's okay.	114:13-118:3 FRE 401, 403 Irrelevant	

Q. I don't have that.
A. I have one. You can have it. I have a copy.
Q. I'll look at the copy. I'll let you look at the exhibit. How's that? Can I look at your copy? Thank you.
What is this document?
A. This is our informed consent for repair of pelvic organ prolapse.
Q. All right. Is this a document that you discussed with Ms. Carlson?
A. Yes.
Q. How do you go through this document with her?
A. So the process of going through it is to either, you know, have the patient first read through the document and then we go through and circle specifically based on the compartment that is prolapsing, talking about her underlying diagnosis, talking about the indications of what we're trying to do in surgery, discussing the possible risks, making sure that she's either, you know, had the information -- she's had the

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opportunity to read it, making sure it's either been read to her, if she's had any questions to ask us about it, and then asking her to sign it if she would like to proceed with surgical therapy.
Q. Okay. And she signed that document on the second page?
A. Yes, she did.
Q. And who's the witness signature?
A. My physician assistant, Amber Herr.
Q. Okay. You sign on the bottom line as well?
A. Correct.
Q. All right. And on the front page of the form it says, the risks of this procedure include but are not -- include but not limited to are, and then it has a bunch of bullet points, right?
A. Correct.
Q. All right. Did you -- is it your practice back in July of 2010 to actually read all those to the patient or was it your practice to have the patient read that to themselves or --
A. I don't recall in 2010.
Q. What's your practice today?
A. The practice today, all patients get

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this. They have an opportunity to review it. If -- as we review it, I will either read the

document to them. My physician assistant may read the document to them. When I come in to counsel them, question if they have any comments, concerns, clarifications, and then ask if they would like to sign the consent form.
Q. And one of the risks listed in this form is possibly no improvement or only temporary improvement in urine control, correct?
A. Correct.
Q. One of the other risks listed here is possible pain or discomfortable with sexual intercourse?
A. Yes.
Q. Is that correct?
And then the last one says, if implant is used, local irritations of wound and/or foreign body response could occur. This response could result in extrusion, erosion, fistula formulation or inflammation, correct?
A. Yes.
Q. And then further on down, it has the practical alternatives to this procedure include, and the first one is observation, do nothing and

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accept the consequences of patient's condition, correct?
A. Yes.
Q. Is it fair to say that her prognosis, if she didn't have the surgical repair, would be -- well, strike that.
What would her prognosis have been without undergoing procedure?
A. She would continue with her current symptoms that she currently has at a bothersome scale, six out of ten.
Q. Okay. And those symptoms could potentially worsen as well?
A. They could.
Q. The second alternative listed there is use of artificial supports (pessaries), correct?
A. Correct.
Q. And she had tried those, correct?
A. Yes.
Q. And she found them very uncomfortable, according to your record?
A. Correct.
Q. And then lastly was Kegel exercise, correct?
A. Correct.

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Q. And I think you testified earlier -- are those effective treatments for Grade III prolapse?
A. For Grade III prolapse, it's marginally

effective. Q. And when was the next time you saw this patient, Doctor? A. The next time was on July 8th, 2010. Q. All right. Okay. And according to that record -- do you have that in front of you, Doctor? A. Yes. Q. Okay. Under the heading subjective, is that a heading -- strike that. What information do you put under the subjective heading? A. The reasons for her visit. Q. Okay. It says, Ms. Carlson returns today for follow-up and further discussion regard -- regarding surgical therapy? A. Yes. Q. And says, she is interested in proceeding with reconstructive surgery to resolve her pelvic organ prolapse. She has met with Dr. Stein. She would like to retain her uterus, if		
mk070214, (Pages 120:11 to 121:4) 120 Did you see Ms. Carlson yourself this visit? A. Yes. Q. All right. And do you have any independent recollection of what you discussed with her or things she said to you or that you said to her? A. Only things that are documented in the note. Q. Okay. All right. And there's reference in this record to the urodynamic testing from March 2nd, 2009? A. Correct. Q. Correct? And the significance of those findings 121 were what? A. She had a Grade III cystocele. She did not have any stress incontinence with the prolapse reduced.		
mk070214, (Pages 121:22 to 122:19) 121 A. I don't recall those conversations. Q. Okay. All right. Turning to the next page of the document under the objective section. A. Okay 122 Q. It says, more than half of today's 30-minute visit was spent in discussion with patient. The indications, alternatives, risks and	121:23-122:19 FRE 401, 403 Irrelevant	

benefits of pelvic reconstructive surgery were reviewed in detail. She verbalized her understanding and wishes to proceed with surgery. In parentheses, you have anterior repair, posterior repair, plus or minus graft, end parentheses. It says, we discussed the various graft materials. She's aware that her overactive bladder symptoms will likely persist after prolapse surgery. Did I read all that correctly? A. Correct. Q. All right. It says you discussed the various graft materials. What materials would you have discussed with her at this visit? A. We discussed biological grafts and synthetic materials.		
mk070214, (Pages 123:5 to 157:157:5) 123 Q. Yeah. Was there any decision made about what graft materials to use with respect to Ms. Carlson at this visit? THE WITNESS: Typically, if someone is maintaining their uterus and they have any type of uterine descensus, then a synthetic-based Uphold device material is what I would use. BY MR. SULLIVAN: Q. It says, she is aware that her overactive bladder symptoms will likely persist after the surgery. So that was something you particularly emphasized to her, was it not? A. Yes. Q. All right. And then down -- the impression section contains your diagnoses, correct? A. Yes. Q. And had any of those diagnoses changed? 124 A. The only thing I said was mild uterine descensus. Q. Then under plan, again, you noted that an operative consent was obtained today emphasizing the enumerated risks? A. Yes. Q. And that consent form is the second consent form contained in Exhibit 3? A. Yes. Q. All right. That was signed by Ms. Carlson as well as yourself on -- A. Yes. Q. -- July 8th, 2010? A. Yes.	124:3-124:25 FRE 401, 403 Irrelevant	

Q. Do you know why you had her do a second informed consent form? A. I believe the reason she decided not to have surgery at first, there was either some psychosocial family issue going on, so she deferred surgery. So when someone decides to come back in to reproceed with surgery, it's as if they're starting all back over again to clarify again what we're doing, why we're doing it, what the associated risks, to make sure that they do understand. 125 Q. All right. And was the next time you saw Ms. Carlson at her surgery? A. Yes. Q. And is your operative note for the surgery contained in Exhibit 2 -- A. Yes. Q. -- of your record? Okay. And is that record the one with the heading has the Carolinas Medical Center in bold print? A. Yes. Q. It says, operative/procedure documentation? A. Yes. Q. Okay. Was this a report you drafted? A. Yes. Q. And you do that by dictating it? A. Correct. Q. Okay. Were there any complications during the course of the procedure? A. No. Q. It says -- according to the operative report, it has Dr. Stein listed as an assistant; do you see that? A. Correct. 126 Q. What was Dr. Stein's role in the surgery? A. Usually for pelvic organ prolapse surgery, an assistant is often needed for retraction; in addition, this is predominantly Dr. Stein's patient who she's been following for many years, who knows the patient the best. There was possibility that hysterectomy may have been needed. That predominant decision would have been Dr. Stein's, whether there was some other type of uterine pathology. So having her there was integral to the operation. Q. So prior to this point, Doctor, prior to the time of this surgery, Ms. Carlson was at a Grade III cystocele, correct? A. Correct.	126:13-127:17 FRE 403	

Q. Her symptoms had -- her pelvic organ prolapse had been symptomatic since about 2008, correct? A. Correct. Q. And those symptoms had been worsening? A. Yes. Q. Kegel exercises at that point were not a good option for her? A. Correct. 127 Q. And she tried a pessary? A. Yes. Q. And that had not been satisfactory to Ms. Carlson, correct? A. Correct. Q. And so at that point, did you recommend the surgery to Ms. Carlson? A. I believe at her initial visit, Dr. Stein had already discussed with her about having surgical repair, and Dr. Stein wanted her to see me to more than likely assist in the surgery or help out regarding different prolapse. Q. Okay. So you understood that Dr. Stein had already discussed the surgery with -- A. Correct. Q. -- Ms. Carlson before you even saw her? A. Correct. Q. When you were discussing the various graft materials with Ms. Carlson back in your July 8th visit before the surgery, did you show her samples of what the material looked like? A. Typically, I do. That's my normal practice to show them biological materials, in addition to synthetic materials. Q. Okay. That was your practice back in 128 July of 2010 as well? A. Correct. Q. And did you have a sort of a standard speech that you would give to patients about the mesh materials? A. Right. Q. What was that? A. Typically, in discussing with someone regarding prolapse, we talked to them about the native tissue repairs, which is using their own natural tissues. In utilizing that type of repair, the results have shown over time in the anterior compartment 40 percent of people will have some recurrence in their lifetime. Other options to try to minimize that are using other materials, including biological materials. Whether that's your own body's tissue, which may be very challenging due to the	Needlessly presenting cumulative evidence 127:18-129:7 FRE 401, 403 Irrelevant	

harvesting, consequently, you can use human tissue. You can also use materials from animals with the goal of it being an interpositional graft to allow that material to resupport that area, trying to decrease the recurrence rate from 40 percent to be less. Other alternatives are utilizing 129 synthetic-based materials. Synthetic-based materials are inert, meaning that they're permanent in nature. They allow the body to integrate within the structure around the material. Q. Was native tissue repair an option for Ms. Carlson's cystocele repair? A. Yes, it was discussed with her. Q. Okay. And why was that course not chosen? A. Well, it was chosen. We did perform an anterior colporrhaphy. Q. Okay. Using native tissue? A. Correct. Q. All right. So you also did the Uphold procedure? A. Correct. Q. So why did you choose to use Uphold? A. Because in her situation at the time of surgery, she had uterine descensus, so the apex was coming down. She had a desire to maintain her uterus, and trying to decrease the risk of recurrence for cystocele, you need to have a very good strong support of the apex. So by using the Uphold strap support going to bilateral sacrospinous ligaments that secures to the cervix 130 provides excellent apical support. In addition, by elevating the cervix, it took care of the rectocele because the rectocele was an apical rectovaginal defect. So trying to provide long-term stability and decrease recurrence from her apex in the posterior and anterior, that was the best option for her. Q. Doctor, do you feel comfortable prior to this surgery that -- that Ms. Carlson understood the potential risks? A. I believe to the best of our ability, going through the consent process, which includes from the -- each time we saw her and reviewing the documents, she had opportunity, you know, to ask questions, so yes. Q. All right. And were you confident at the time of the surgery that Ms. Carlson understood the potential benefits of the procedure? A. I would hope. We did discuss the risks and the benefits.	130:8-131:6 FRE 401, 403 Irrelevant	

Q. Okay. Would you ever perform surgery on a patient if you didn't feel that patient adequately understood the risks and benefits of the procedure? A. As long as patients verbalize it and 131 are cognitively intact and they're desiring to undergo things under their own accord and have given consent, yes. Q. Okay. That's what Ms. Carlson did, right? A. Correct. Q. Did the procedure you performed on Ms. Carlson take place under general anesthesia? A. Yes. Q. Okay. How long was the procedure? A. I don't recall. Q. Does your operative note reflect that? A. No. Q. And did you have any problems placing the Uphold mesh in Ms. Carlson? A. No. Q. Was this particular surgery more difficult or complex than other pelvic organ prolapse surgical procedures that you performed? A. No. Q. Do you know when Ms. Carlson left the hospital after this procedure? A. The day after. Q. Upon placing the Uphold mesh and during the course of the surgery, were you able to 132 visually determine whether the surgery was successful? MR. FABRY: Objection, form. THE WITNESS: As for -- yes. You can tell based on the anterior colporrhaphy, based on the elevation of the cervix and uterus, she had very good support apically, anteriorly and posteriorly. BY MR. SULLIVAN: Q. All right. In other words, her pelvic organ prolapse was reduced and supported? MR. FABRY: Objection, form, leading. THE WITNESS: Correct. BY MR. SULLIVAN: Q. Yes? A. Yes. Q. Were you pleased with the result at the conclusion of the surgery? A. I was satisfied with the result. Q. All right. And then you saw	131:24-132:8 FRE 401; 403 use of “successful” is misleading	

Ms. Carlson postoperatively, correct? A. Yes. Q. When was the first time you saw Ms. Carlson postoperatively? A. She was seen on 7/27/10. At that 133 visit, she was seen by my physician assistant. Q. Okay. Was that Ms. Herr? A. Correct. Q. Did you see Ms. Carlson that day as well or no? A. I don't recall. Q. All right. And under the subjective section of the report, it notes that Ms. Carlson is returning for follow-up after pelvic reconstructive surgery. She has done quite well, but had some pain at the right side of her introitus. Initially, her pain was eight out of ten. Now it is three out of ten. She has been using Estrace vaginal cream with benefit. She's not had any vaginal bleeding, fevers or calf pain. Do you see that? A. Yes. Q. And then on examination -- well, strike that. Pain at the right side of the introitus, is that a common or uncommon finding after surgery? A. The -- at the time of surgery, we utilize a retractor system where it has hooks, and part of those hooks are sharp that are used to be 134 placed inside the vaginal introitus to provide retraction and exposure. So those hooks can create a -- a mark. They can penetrate the skin, sort of a small irritation. Q. Okay. A. So -- Q. Is that what you attributed her introitus pain to? A. Yes, based on Amber's definition where she had a small divot in the vaginal tissue at 7:00 just inside the introitus, no sign of infection, there's no bleeding, but it is tender. Q. Would the location of that, what she calls a small divot, be consistent with the retractors? A. Yes. Q. Okay. Is there -- it notes she's been using Estrace vaginal cream. Is that something that you had prescribed? A. Typically we encourage patients to use	132:10-16 FRE 611 Leading	

Estrace vaginal cream, you know, prior to surgical intervention in preparation for surgery and then also after surgery.
Q. And why is that?
A. We're trying to decrease the risk of

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exposure, if we're using synthetic material, trying to improve the health of the vaginal tissue.
Q. Does it help the vaginal tissue to heal?
A. There are good healing properties of it, yes.
Q. Were there any concerning signs or symptoms at this initial postoperative visit?
A. No.
Q. So at this point, did you have -- was it your belief that she was doing well?
A. Amber Herr felt she was doing well.
Q. Do you have any reason based on the record to disagree with that?
A. No.
Q. Okay. And when did you next see or when did Ms. Carlson next visit your office?
A. The next visit was on August 12th, 2010.
Q. All right. It was about a month after the surgery?
A. It's probably three weeks.
Q. Okay. So under the subjective heading, it says, Ms. Carlson returns for follow-up four weeks status post vaginal paravaginal repair; do

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you see that?
A. Yes.
Q. All right. Notes doing well; do you see that?
A. Yes.
Q. She feels she's greatly improved. She is dry all the time and wears no pads. She voids every one to two hours; nocturia, zero to one time, and on a bothersome scale of zero to ten, frequency, nocturia and urgency are zero out of ten; incontinence is two out of ten. So she has some incontinence with vigorous activity/sneezing. It says, she is satisfied and would recommend the therapy to a friend. Did I read all that correctly?
A. Correct.
Q. All right. Those frequency, nocturia and urgency symptoms, why were you monitoring those?
A. Prior to the plan -- part of my

practice is after interventions, I have patients fill out a questionnaire, and this questionnaire is her answers on that. They typically fill it out prior to us seeing them for that day so they can fill it out in their own -- they can do it

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unbiased.
Q. Then it notes she has some increased right vulvar irritation and has been applying estrogen cream to the area as well as Lidocaine. What is right vulva irritation?
A. So the vulvar area is where the labia majora and minora or, in other words, the opening to the vaginal area.
Q. She had some irritation there?
A. Correct.
Q. And did you have an understanding at that time as to what the cause of that irritation was?
A. Based on review of prior notes, it was apparent that it was likely due to the Lone Star retractor hooks.
Q. And you examined Ms. Carlson at this visit?
A. Yes.
Q. And you noted that she had atrophic external genitalia?
A. Yes.
Q. What does atrophic mean?
A. Typically, signs of loss of estrogen, so that the tissue becomes friable, a little bit

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more easily bruisable or irritated. The vaginal area can be sometimes narrowed.
Q. Okay. So is that a significant finding in terms of her complaints of this irritation?
A. Based on my notation, I think she was complaining mainly sort of not on the external genitalia, but more just on the inside of the vulvar area.
Q. It says, she has some slight attachment of the labia minora and majora. What do you mean by that?
A. That's signs of atrophy where both of those two structures fuse together from loss of estrogen.
Q. Are those -- is that a significant finding in terms of potential for future complications?
A. Only for patients if they're having issues regarding dyspareunia or pain, sexual function, if they have urogenital atrophy.
Q. Okay. And then it says, no obvious

sign of ulceration, no irritation of the area. Is that referring back to the labia minora and majora?
A. Correct.
Q. It says, pal -- palpation of the vulva

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shows no trigger point tenderness.
A. Correct.
Q. She complains of some mild irritation of the labia minora, labia majora, superficial on the right side. Did you have a -- did you come to any conclusion as to what the cause of that irritation was?
A. My impression that it could be possibly related to the cleansing that was done at the time of surgery with her preparation. It could be also possibly the retractors or she could possibly have a condition that's called vulvodynia.
Q. What's vulvodynia?
A. Vulvodynia is a -- is a pain condition of the vulvar tissues.
Q. What causes that condition?
A. They don't know at this point in time.
Q. Okay. So that was sort of all listed in impression Number 2 as your --
A. Correct.
Q. -- essentially your differential diagnosis on -- on that particular complaint?
A. Correct.
Q. All right. And you note she has no cystocele, no rectocele. She has excellent apical

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support, correct?
A. Yes.
Q. And that's -- is that indicative of the procedure being successful?
A. Yes.
Q. Okay. Your impression Number 1 is, she is doing well four weeks status post vaginal reconstructive surgery with resolution of prolapse, meaning -- resolution prolapse meaning she doesn't have prolapse anymore, correct?
A. Correct.
Q. And you talked about Number 2 and Number 3 says, no voiding dysfunction. So her urinary or overactive bladder symptoms that she had prior to the surgery weren't presenting at this time, correct?
A. Well, it's, in essence, no voiding dysfunction, I'm meaning that she's able to empty her bladder adequately. Her post residual was zero.
Q. So at this point in time, did you feel she was doing well?

23 A. Yes.
24 Q. Were there any complications at this
25 point?

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1 A. She was just complaining of right-sided
2 vaginal irritation.
3 Q. Okay. Which was, in your mind,
4 attributable probably to the retractors?
5 A. Yes.
6 Q. Okay.
7 A. Or possibly maybe she could have
8 developed, you know, new onset vulvodynia.
9 Q. And when did you next see Ms. Carlson?
10 A. She was next seen in September 14th,
11 2010.
12 Q. Okay. Was she seen by you at that time
13 or your physical -- I'm sorry -- your physician's
14 assistant or both?
15 A. It was likely both.
16 Q. Okay. All right. And at this time
17 under subjective, it says, Ms. Carlson returns for
18 follow-up now two months status post vaginal
19 reconstructive surgery. She developed some
20 right-sided vulvodynia -- vulvodynia, but is now
21 doing well and her labial pain has improved. She's
22 not currently using Estrace scream. She denies
23 vaginal bleeding or pain. And it says, she's had
24 three episodes of urinary urgency and difficulty
25 getting to the bathroom in time, correct?

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1 A. Yes.
2 Q. So the irritation that she -- that had
3 been noted on the prior visit was no longer
4 present?
5 A. That I don't -- I don't know -- recall.
6 Q. It had improved?
7 A. Yes.
8 Q. That was your impression Number 1 on
9 the next page, right?
10 A. Yes.
11 Q. Okay. All right. In your impression,
12 you also note, she is doing well status post
13 reconstruct -- vaginal reconstructive surgery, and
14 Number 3, you note urinary urgency, correct?
15 A. Yes.
16 Q. Did you have any discussion with
17 Ms. Carlson at that time about the urinary urgency
18 symptoms?
19 A. Yes. Dietary modifications and using
20 Prelief antacid supplements.
21 Q. Did you draw any conclusions at that
22 point in time as to why she was having urinary
23 urgency at this time?

24 A. She had had overactive bladder symptoms 25 prior to surgery. We counseled her that she may 143 1 have it after surgery. It is -- it is apparent two 2 months after surgery she still has overactive 3 bladder. 4 Q. Okay. All right. And under your plan, 5 you note that she should have an office follow-up 6 in one year or follow-up as needed with any 7 problems, correct? 8 A. Correct. 9 Q. And she was cautioned about lifting 10 more than 15 or 20 pounds; otherwise, she may 11 return to all normal activities, correct? 12 A. Yes. 13 Q. Was that your last visit with 14 Ms. Carlson? 15 A. Yes. 16 Q. Did you ever speak with her after that 17 visit? 18 A. No. 19 Q. Did she ever call you to complain of 20 any new symptoms? 21 A. No, not that I know of. 22 Q. So at the time of your last visit with 23 Ms. Carlson, what was your assessment of how she 24 was doing after the surgery? 25 A. She was doing well. 144 1 Q. Okay. Do you have any knowledge, 2 Doctor, as to the injuries Ms. Carlson is claiming 3 in this case? 4 A. No. 5 Q. And we marked your curriculum vitae as 6 Exhibit 5. I don't know if you have a copy of that 7 with you. 8 A. Okay. 9 Q. Or do you? Do you have a copy? 10 A. Yes. 11 Q. All right. Why don't I give you the 12 exhibit. I'll take your copy. Thank you. 13 Just -- you mentioned this is up to 14 date through, I think you said the beginning of 15 2014? 16 A. Correct. 17 Q. All right. Is there anything 18 additional that would be included in order to 19 update it to the present? 20 A. Several different presentations, maybe 21 a couple articles, updated honors and awards, new 22 research studies. 23 Q. Can you describe for me your practice, 24 your patient population?	143:16-143:21 FRE 401, 403 Irrelevant, misleading 144:1-144:4 FRE 401, 403 Irrelevant, misleading	

25 A. So I have three really separate

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1 practices. In regards to Women's -- the Women's
2 Center for Pelvic Health practice, it's able-bodied
3 females who have pelvic organ prolapse, urinary
4 incontinence, voiding dysfunction. In regard --
5 and that's at the location we're at today.
6 I do also have a male incontinence
7 practice at McKay Urology, and that's for men with
8 urinary incontinence. And then I also have a
9 practice at Carolinas Rehabilitation, which is a
10 neurourology practice, patients who have spinal
11 cord injury, Parkinson, brain injury, stroke that
12 lower urinary tract, urinary incontinence,
13 overactive bladder, voiding dysfunction.
14 Back in 2010, there was no Women's
15 Center For Public Health. So I saw all the male
16 and female patients at McKay.
17 Q. I see. Can you just -- briefly,
18 Doctor, can you just describe for us your
19 educational background, start with college.
20 A. So college at University of Notre Dame.
21 Subsequent to that was at University of Cincinnati
22 Medical School. Then surgical internship followed
23 by urology residency up at University of Michigan.
24 And then fellowship training at University of
25 Texas, Houston, in female urology, voiding

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1 dysfunction, neurourology and urodynamics.
2 Q. What's fellowship training?
3 A. It's extra training beyond standard
4 urology that tries to dedicate your interest and
5 focus into a particular urologic specialization.
6 So my area was really the lower urinary tract.
7 Q. How long have you been practicing,
8 Doctor?
9 A. I've been in Charlotte here since 1995.
10 Q. And are you board certified in urology?
11 A. Correct, board certified in urology and
12 female pelvic medicine reconstructive surgery.
13 Q. How do you become board certified in
14 those areas?
15 A. For urology, you need to go through an
16 ACGME approved residency program. You need to pass
17 written and then oral board certified tests,
18 maintain your certification and then recertify
19 every ten years.
20 For the female pelvic medicine
21 reconstructive surgery, you have to show a case log
22 that shows you're specializing into women's health
23 within the various surgical procedures, review a
24 complications list, and then also sit for a
25 certifying exam and pass the exam.

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1 Q. Doctor, did you -- do you recall
2 speaking with any Boston Scientific Corporation

sales representatives regarding the Uphold product at any time prior to Ms. Carlson's surgery? A. I believe that during training, you know, the initial training, there were sales representatives there. So I'm sure that with my initial training, and then subsequent with follow-ups, I've had discussions with representatives. Q. When you say at training, you're referring to the training that was put on by Boston Scientific Corporation? A. Correct. Q. And in treating patients, do you rely on what sales representatives tell you or do you rely on your own expertise and experience? THE WITNESS: So there's a variety of things we utilize; but, clearly, it's my own expertise, understanding of the literature, understanding of my prior experience, my background, surgical training and then information gathered from variety of resources, whether that be the company, the instructions for use, the 148 hands-on, colleagues, medical literature, journals. BY MR. SULLIVAN: Q. And, Doctor, do your interactions with companies' manufacturers' sales representatives replace your own independent medical judgment in treating a patient? A. No. MR. SULLIVAN: Objection to form, leading. BY MR. SULLIVAN: Q. Specifically with respect to the Uphold product, do you recall having any communication with Boston Scientific Corporation sales rep -- representatives? A. I don't recall specifically. Q. Do you recall receiving any written information regarding the Uphold product from any Boston Scientific Corporation sales representatives? A. I don't recall other than information that would have been shared regarding from the company as far as invitation to the initial training sessions and then follow-up after that. Q. Would that also include information that you may have received to teach some of these 149 trainings? A. Correct. Q. With respect to your contracts with Boston Scientific Corporation, we've marked as	148:3-7 FRE 611 Leading	

Exhibits 9 and 10. What did you understand -- strike that.
Let me clarify first. You said one of these was unexecuted or unsigned, and that was the June 2014 version --
A. Correct.
Q. -- marked as Exhibit 11?
A. Yes.
Q. So do you have a current contract with Boston Scientific Corporation?
A. No.
Q. And when was the last time you were under contract as a consultant with Boston Scientific Corporation?
A. I believe it's 2011.
Q. Okay. And what did you understand the scope of your consulting agreement to be?
A. The scope of the agreement actually had several areas to be able to train, speak, advise Boston Scientific personnel on technology, developments and procedures in the field; to

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consult with and advise Boston Scientific employees on current issues in the field; to train and speak on Boston Scientific's behalf on topics relevant to the field; to consult and advise other medical advisers, consultants and other Boston Scientific designated professionals on current medical issues in the field; and to develop educational materials for Boston Scientific.
Q. And you mentioned that you taught at Boston Scientific Corporation trainings for other physicians, correct?
A. Correct.
Q. What other services did you provide?
A. My services were training, proctoring and precepting.
Q. And what's proctoring?
A. So proctoring -- proctoring and precepting are very similar types of terms. So precepting is where other physicians will come in and sort of come to your practice. You will spend dedicated time going through education, training, the background. They may see how you work up patients, evaluate patients and then they have the opportunity of watching you operate. And then afterwards, you go through and discuss cases with

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them.
Whereas, proctoring patient -- proctoring is where a surgeon who has been trained on the product would like to have an additional observer at the time when they're doing it to maybe guide them in other steps or to provide reassurance or questions and queries to their operative

techniques, their setup, their preop and postop evaluation of patients. Q. And when you performed proctoring or preceptorships, were you compensated for your time spent doing that? A. Yes. Q. And when you perform the training for other physicians, were you compensated for your time in doing that? A. Yes. Q. Okay. And did any of those payments influence -- strike that. Did any of those payments influence your decision to use Uphold in Ms. Carlson's case? A. No. Q. Did they influence your decision to use Uphold in any other case? A. No. 152 Q. When Ms. Carlson first came to see you, did she have a significant problem with her pelvic organ prolapse? THE WITNESS: Yes. BY MR. SULLIVAN: Q. And was her condition adversely impacting her daily life at that point? A. Yes. Q. And, Doctor, did you offer -- did you discuss with Ms. Carlson any nonsurgical options to try and improve her condition? THE WITNESS: Discussed observation and pelvic physiotherapy. BY MR. SULLIVAN: Q. And were you available to Ms. Carlson if she had questions or concerns about any aspect of her condition or -- or treatment options? THE WITNESS: Yes. BY MR. SULLIVAN: 153 Q. Did you give Ms. Carlson as much time as she needed to make sure she understood the options and the course of treatment? A. Yes. BY MR. SULLIVAN: Q. And as part of your care and treatment of Ms. Carlson, did you ultimately choose to use the Uphold to help treat her pelvic organ prolapse? MR. FABRY: Objection, form, asked and answered. THE WITNESS: Yes. BY MR. SULLIVAN:	152:1-6 FRE 403 Asked and Answered, needlessly cumulative testimony 152:11-153:13 FRE 403 Asked and Answered, needlessly cumulative testimony	

Q. At the time of her surgery, Doctor, did you have adequate information on the use of Uphold to properly perform the procedure? MR. FABRY: Objection, form, and asked and answered and foundation. THE WITNESS: Yes. BY MR. SULLIVAN: Q. And at the time of Ms. Carlson's surgery, did you have adequate information to properly evaluate the risks and the benefits of the Uphold for Ms. Carlson? 154 THE WITNESS: Yes. BY MR. SULLIVAN: Q. Regarding the risks of the procedure that you performed on Ms. Carlson at the time of that surgery, you were aware or were you aware of all the risks included in the Uphold directions for use that have been marked as an exhibit earlier? THE WITNESS: Yes. BY MR. SULLIVAN: Q. At the time of your surgery on July 16th, 2010, you were aware of the risks of erosion? A. Yes. BY MR. SULLIVAN: Q. Were you aware of the risks of recurrence? THE WITNESS: Yes. BY MR. SULLIVAN: 155 Q. Were you aware of the risks that her urgency symptoms may continue? A. Yes. BY MR. SULLIVAN: Q. Were you aware of the risk of urinary incontinence? A. Yes. BY MR. SULLIVAN: Q. Were you aware of the risk of pain? A. Yes. BY MR. SULLIVAN: Q. Did you inform Ms. Carlson of these risks prior to the procedure? A. Yes.	153:15-154:14 FRE 401, 403, 703 Irrelevant, needlessly cumulative testimony 153:15-154:2 FRE 703 Foundation 153:14-155:16 FRE 403 needlessly cumulative testimony FRE 611 Leading 155:17-155:22 FRE 401, 403 Irrelevant	

23 BY MR. SULLIVAN: 24 Q. Based on your clinical experience, 25 Doctor, and your medical training, do you believe 156 1 Ms. Carlson was an appropriate candidate for the 2 Uphold? 3 A. Yes. 6 BY MR. SULLIVAN: 7 Q. Doctor, has any of your testimony today 8 been colored or influenced by your -- any payments 9 you received from Boston Scientific for the 10 trainings you provided, the proctors -- 11 proctorships or preceptorships that you performed? 12 A. No. 13 Q. Do you believe consulting roles such as 14 you had with Boston Scientific Corporation provides 15 any benefit to your patients? 17 THE WITNESS: The more informed that a 18 physician is in regards to all the details of any 19 type of surgical procedure will obviously improve 20 the aspect and understanding. 21 So I think that as a continual learner, 22 to continue to learn and be educated and be able to 23 learn from others to gain knowledge of their 24 experiences what they've been going through, which 25 is part of this networking and sharing of 157 1 knowledge, is definitely a value to not only my 2 patients, but my future patients, and also the 3 other colleagues that are there at the time. 4 MR. SULLIVAN: Okay. Thank you, 5 Doctor. I have no more questions.	155:23-156:3 FRE 403 Needlessly cumulative	
mk070214, (Pages 172:14 to 172:20) 172 14 mentioned earlier. Is there a bio -- rephrase it 15 this way. In 2010, was there a biological implant 16 option that would serve the same purpose as the 17 Uphold? 18 MR. SULLIVAN: Objection. 19 THE WITNESS: For the Uphold, the 20 answer would be no.		
mk070214, (Pages 176:12 to 176:19) 176 12 Q. And as a physician, do you feel it's 13 important for you to know the rate of occurrence 14 for the risks associated with Boston Scientific's 15 products? 16 A. I think within the space of all pelvic 17 floor reconstruction no one has rates, so that has 18 not been the standard of care in regards to pelvic 19 prolapse.	176:12-19 FRE 403 Non-responsive, FRE 703 Foundation	*mk070214, (Pages 175:14 to 176:11)* *175* *14 Q. And you did receive some monetary* *15 benefits. You were compensated for your time* *16 relative to Boston Scientific pelvic mesh products,* *17 correct?*

		18 *A. I was --* 19 *MR. SULLIVAN: Objection.* 20 *THE WITNESS: -- compensated for my* 21 *time of training regarding Boston Scientific* 22 *products.* 23 *BY MR. FABRY:* 24 *Q. Okay. And as a physician, did you* 25 *reasonably rely on Boston Scientific Corporation to* 176 1 *advise you of all the risks associated with their* 2 *mesh products?* 3 *A. Yes.* 4 *Q. As a physician, do you feel it's* 5 *important for you to know the severity of* 6 *complications for Boston Scientific's products?* 7 *A. Yes.* 8 *MR. SULLIVAN: Objection.* 9 *BY MR. FABRY:* 10 *Q. And that would include the Uphold?* 11 *A. Yes.*
mk070214, (Pages 202:18 to 203:13) 202 18 Q. And, Doctor, I think you testified that 19 you are a member of AUGS, correct? 20 A. Yes. 21 Q. What's AUGS stand for again? 22 A. The American Urogynecological Society. 23 Q. And are you a member of SUFU? 24 A. Society of Urodynamics and Female 25 Urology. 203 1 Q. Are you familiar, Doctor, with the AUGS 2 SUFU position statement from 2013 -- 3 A. Yes. 4 Q. -- on polypropylene material in mesh? 5 A. Yes. 6 Q. Okay. Are you aware that those 7 organizations issued a statement saying, 8 polypropylene material has been used in most 9 surgical specialties for over five decades in 10 millions of patients in the U.S. and the world? 11 A. Yes. 12 Q. Do you agree with that statement? 13 A. Yes.	203:1-203:13 FRE 802, 803 Hearsay, no exception FRE 403 Unduly prejudicial FRE 703 Foundation	

mk070214, (Pages 203:19 to 206:2) 203 19 Q. What sort of medical applications has 20 polypropylene had in the body over the past five 21 decades? 22 MR. FABRY: Objection, foundation. 23 THE WITNESS: It has a variety of uses 24 that it's been used upon, but within the general 25 surgery literature, abdominal herniorrhaphies have 204 1 been predominantly used; within the sort of 2 urogynecology aspect for abdominal sacral colpopexy 3 for many, many years they've utilized 4 polypropylene. 5 There are other surgical applications 6 that have been utilized in different disciplines, 7 but predominantly the ones that I've been aware of 8 are the abdominal and pelvic floor related. 9 BY MR. SULLIVAN: 10 Q. Are you aware of whether the American 11 Urologic Association has endorsed the use of 12 polypropylene mesh to treat pelvic organ prolapse 13 repair in appropriate patients? 14 A. They have a -- they have a position 15 statement. I don't know whether they've endorsed. 16 Q. Okay. 17 A. They don't endorse things. 18 Q. Okay. So are you aware that the 19 American Urologic Association issued a statement 20 November 2011? 21 A. Yes. 22 Q. Okay. And in that statement stated, 23 mesh may improve long-term anatomic results of 24 surgery as compared to nonmesh repairs for some 25 types of prolapse? 205 1 A. Yes. 2 Q. Do you agree with that statement? 3 A. Yes. 4 Q. Do you know that in that same 5 statement, the AUA said -- said, certain patients 6 may benefit from mesh techniques and the use of 7 mesh techniques should be a choice that is made 8 after a careful discussion between surgeon and 9 patient? 10 A. Yes. 11 Q. Do you agree with that statement? 12 A. Yes. 13 Q. And are you aware that the AUA also 14 said, it is also important to recognize that many 15 of these complications are not unique to mesh 16 surgeries. They are known to occur with nonmesh 17 pelvic organ prolapse procedures as well?	203:19-204:8 FRE 703 No foundation to offer opinion on general usage outside of practice specialty	

18 A. Yes. 19 Q. You agree with that, right? 20 A. Yes. 21 Q. In fact, you testified earlier that all 22 of the risks associated with mesh pelvic organ 23 prolapse repair are associated with native tissue 24 repair other than erosion, correct? 25 MR. FABRY: Objection, form, asked and 206 1 answered. 2 THE WITNESS: Correct.		

Exhibits

1. Exhibit 2 – McKay Urology office notes
2. Exhibit 3 – Informed Consent form for Ms. Carlson
3. Exhibit 4 – Ms. Carlson's Billing Records
4. Exhibit 5 – Dr. Kennelly's Curriculum Vitae
5. Exhibit 8 – Cross-Notice of Deposition
6. Exhibit 9 – Contract with Boston Scientific from 6/1/09
7. Exhibit 10 – Contract with Boston Scientific from 8/3/11
8. Exhibit 11 – Unexecuted Contract with BSC from 6/26/14
9. Exhibit 12 – Confirmation of Service from 9/25/11
10. Exhibit 13 – Confirmation of Service from 10/16/11
11. Exhibit 14 – 2011 1099
12. Exhibit 15 – Pelvic Floor Institute, Women's Health Business of BSC Faculty Guide from June 2010
13. Exhibit 16 – Uphold DFU
14. Exhibit 17 – FDA Public Health Notification regarding serious complications associated with transvaginal placement of surgical mesh in the repair of pelvic organ prolapse and stress urinary incontinence.

DATED: June 26, 2015

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 26, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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